Synergy*UHD4*™ System
Instructions for Use Manual

The Arthrex Synergy*UHD4*™ System Camera Control Unit and Camera Head User's Guide provides important information for the safe operation of all components of the Synergy*UHD4* Camera System, including accessories. Read this User's Guide thoroughly prior to using this system and keep it in an easily accessible place for use by all operating personnel. Read and follow all safety warnings, cautions and precautions.

AR-3200-0020
AR-3200-0021
AR-3200-0022
AR-3200-0023

AR-3210-0018
AR-3210-0021
AR-3210-0022
AR-3210-0023
AR-3210-0025
AR-3210-0026
AR-3210-0028
AR-3210-0029
AR-3210-0030
AR-3210-0031
AR-3210-0032

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This is not a warranty document. For all warranty information, including disclaimers, exclusions, terms, conditions, and related provisions, refer to the "Arthrex U.S. Product Warranty" section of the Arthrex, Inc. website, found at www.arthrex.com whose provisions are incorporated herein by reference.

Table of Contents

1.0 Introduction

It is recommended that personnel study this manual before attempting to operate, clean, and/or sterilize the Arthrex Synergy Synergy*UHD4* System and accessories. The safe and effective use of this equipment requires the understanding of and compliance with all warnings, precautionary notices, and instructions marked on the product, and included in this manual.

The Arthrex Synergy*UHD4* System is comprised of:

- AR-3200-0020 [Synergy*UHD4* Console with Matrix]
- AR-3200-0021 [Synergy*UHD4* Console]
- AR-3200-0022 [Synergy*UHD4* Console with Matrix, HCRI]
- AR-3200-0023 [Synergy*UHD4* Console, HCRI]
- AR-3210-0018 [HD, Synergy*UHD4* Camera Head, autoclavable]
- AR-3210-0021 [HD Synergy*UHD4* C-Mount Camera Head, autoclavable]
- AR-3210-0022 [HD Synergy*UHD4* C-Mount Camera Head, 0 Degree, autoclavable]
- AR-3210-0023 [4K Synergy*UHD4* Camera Head, autoclavable]
- AR-3210-0025 [4K Synergy*UHD4* C-Mount Camera Head, autoclavable]
- AR-3210-0026 [4K Synergy*UHD4* C-Mount Camera Head, 0 Degree, autoclavable]
- AR-3210-0028 [4K Synergy*UHD4* C-Mount w/20 foot cable, autoclavable]
- AR-3210-0029 [4K Synergy*UHD4* Broadband Camera Head, autoclavable]
- AR-3210-0030 [4K Synergy*UHD4* C-Mount Broadband Camera Head, autoclavable]
- AR-3210-0031 [4K Synergy*UHD4* Ultra Camera Head, autoclavable]
- AR-3210-0032 [4K Synergy*UHD4* Ultra C-Mount Camera Head, autoclavable]

NOTE: AR-3200-0020/AR-3200-0022 Synergy*UHD4* Consoles or Camera Control Units (CCU) are identical to AR-3200-0021/AR-3200-0023 CCUs except that AR-3200-0020/AR-3200-0022 incorporate the Matrix PWA for transmission of UHD4 data by fiber optic.

1.1 Intended Use

This system is designed for use by physicians and surgeons and is intended for endoscopic camera use in a variety of endoscopic surgical procedures, including but not limited to, orthopedic, laparoscopic, urologic, sinuscopic and plastic surgical procedures. It is also intended to be used as an accessory for microscopic surgery.

1.2 Contraindications

Do not use the device if endoscopic surgery is contraindicated.

Do not use the device if the environmental conditions for use do not meet the standards or regulations defined in the accompanying documents.

1.3 Warnings and Precautions

The words **WARNING**, **PRECAUTION**, and **NOTE** carry special meanings and they should be read carefully.

WARNING: The safety and/or health of the patient, user, or a third party is at risk. Comply with this warning to avoid injury to the patient, user, or third party.

PRECAUTION: This contains information concerning the intended use of the device or accessory. Damage to the equipment is possible if these instructions are not followed.

NOTE: A note is added to provide additional, focused, information.

1.3.1 WARNINGS

- **This equipment is designed for use by medical professionals completely familiar with the required techniques and instructions for use of the equipment. Prior to using the device, read and follow all warning and**

precautionary notices and instructions marked on the product and included in this manual. Become familiar with the operation and function of this device and associated accessories. Failure to follow these instructions can lead to:

- **Life-threatening injuries to the patient**
- **Severe injuries to the surgical team, nursing or service personnel, or**
- **Damage or malfunction of the device or accessories.**
- Caution: Federal law restricts this device to sale by or on the order of a physician.
- This device is intended to be used by a trained medical professional.
- Biohazard waste, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy.
- Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.
- **In CE Accepting Countries:** Procedures carried out using these devices may be used on the general population.
- **In CE Accepting Countries:** The clinical benefits associated with the use of these devices outweigh the known clinical risks.
- **In CE Accepting Countries:** There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.

1. Do not open or attempt to service this system, as this may void your warranty. There are no user-serviceable parts inside. Removing the cover may introduce an electric shock hazard by exposing you to dangerous high voltages or other risks. If the system malfunctions, return it for service immediately.
2. For the protection of the patient it is recommended that a back-up camera system for the Arthrex Synergy*UHD4* video system be maintained, sterilized, and ready to be implemented.
3. For the protection of the patient it is essential that the endoscopic video system interconnection is complete and produces a viable color picture on the surgical monitor PRIOR to administration of patient anesthesia.
4. Disconnect camera head and endoscope from the patient prior to applying cardiac defibrillation to patient.
5. Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical effect.
6. This device and its accessories are to be used only by physicians and medical assistants under the direction of a physician with appropriate technical qualifications.
7. This device shall only be used with original and manufacturer's accessories and replacement parts. Use of other parts or materials may degrade safety.
8. Do not use in the presence of flammable anesthetics, gases, disinfecting agents, cleaning solutions, or any material susceptible to ignition due to electrical sparking.

9. Equipment grounding is vital for safe operation. Plug the power cord into a properly earthed mains supply outlet whose voltage and frequency characteristics are compatible with those listed on the unit or in this manual. Do not use plug adapters or extension cords; such devices defeat the safety ground and could cause injury.
10. This equipment should not share an electrical outlet or grounding with life supporting or life sustaining equipment.
11. If one or more mains powered units are connected simultaneously to one socket by the means of a distribution box, the sum of the individual leakage currents may exceed the tolerated limits.
12. Before each use, the outer surface of the portions of the Endoscope and any Endoscopically Used Accessory, which are intended to be inserted into the patient, should be checked to ensure there are no unintended

rough edges, sharp edges or protrusions which may cause a safety hazard.

13. Refer to Insufflation Device Instructions regarding safety hazards to patients resulting from gas emboli.
14. The leakage current through the patient could increase when using endoscopes with powered accessories.
15. When Endoscopes are used with Energized Endoscopically Used Accessories, the Patient Leakage Currents may be additive. This is particularly true if a CF Applied Part is used, in which case a Type CF Endoscopically Used Accessory should be used to minimize total Patient Leakage Current.
16. Applied Parts of other ME Equipment used within the configuration for Endoscopic Application shall be type BF or CF Applied Parts.
17. Explosive gas concentrations inside the patient can cause hazards while using High-Frequency Endoscopically Used Accessories.
18. For the protection of service personnel, and for safety during transportation, all devices and accessories that are returned for repair must be prepared for shipment as described in "**Returning the Device"** of this manual. The manufacturer has the right to refuse to carry out repairs if the product is contaminated.
19. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Synergy*UHD4* Video System or shielding the location.
20. NOT for use in an Oxygen Rich Environment.
21. NO Modifications of this equipment are allowed.
22. Connecting any equipment that has not been supplied as part of this ME System to Multiple Socket Outlets may result in increased leakage currents. Use an IEC Approved Isolation Transformer to isolate any such interconnections from the ME System.
23. Before each use or after changing viewing modes/settings the Operator should check to ensure that the view observed through the Endoscope provides a live image (rather than a stored one) and has the correct image orientation.
24. Risk of burns!

    LED Light Engines emit large amounts of light and thermal energy. As a result:

    - Always keep the LED Light Engine in the STANDBY mode when not in use. The endoscope light guide connection can get extremely hot as result of high intensity light, giving rise to high temperatures in front of the light emission window which may cause severe burns.
    - Surface temperatures of the insertion portion of the endoscope as well as light guide connectors on the Camera Control Unit (CCU) and the endoscope rise during use.
    - Potential thermal injury to the patient's tissue and skin may result from prolonged exposure to the intense illumination in small cavities, or if the endoscope's distal end is placed in close proximity with the tissue. This can cause the temperature of the body tissue to rise in excess of 106°F (41°C). Burns or thermal damage to surgical equipment may also result.
    - Avoid prolonged exposure to intense illumination.
    - Use the minimum level of illumination necessary to satisfactorily illuminate the target area.
    - Do not place the endoscope's distal end or light guide connector on the patient's skin, on flammable materials or on heat sensitive materials.
    - Turn the light source off when detaching the endoscope from the light guide cable.
    - Allow the endoscope and light guide cable to cool down after use before reprocessing.

25. High Frequency [HF] electrical surgical instruments may lead to severe patient injuries and/or damage to the endoscope. Care should be taken to ensure that the working element is kept within field of view to prevent accidental burns. A sufficient distance from the tip of the endoscope to

other conductive accessories and instruments should be maintained (10 mm (0.39 in.)) before activating the HF output to prevent burns and damage to the endoscope. Refer to the HF Surgical Device Instructions for proper and safe use.

26. HF surgical instruments may interfere with video images. To prevent such interference, HF equipment and video imaging equipment should be connected to different power supply circuits.
27. Use of Lasers in surgery may result in Eye Damage or damage to the endoscope from reflected laser energy. Refer to the Laser Device Instructions for proper and safe use.
    - When using a laser always wear protective glasses designed for the laser's wavelength.
    - Cover the patient's eyes, or use protective glasses designed for the laser's wavelength.
    - To prevent damage to the Endoscope, the Laser should be activated only after the tip of the laser can be seen through the endoscope.
28. To ensure FCC RF Exposure limits for base station transmissions devices are met, a distance of 20 cm (7.9 in.) or more shall be maintained between the Camera Control Unit (which contains the antennas), and persons during operation. To ensure compliance, an operator closer than 20 cm (7.9 in.) to Camera Control Unit is not recommended.

1.3.2 PRECAUTIONS 

1. United States Federal law restricts sale of this device to or on the order of a physician.
2. Only use the device with Arthrex compatible equipment listed in Section 2.2.
3. Inserting an incompatible Camera Head into the camera receptacle (see Figure 1) can result in damage to the CCU.
4. The warranty becomes void and the manufacturer is not liable for direct or resulting damage if:
    - The device or the accessories are improperly used, prepared or maintained;
    - The instructions in the manual are not adhered to;
    - Non-authorized persons perform repairs, adjustments or alterations to the device
    - Non-authorized persons open the device.
    - Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.

NOTE: Receipt of technical documentation from the manufacturer does not authorize individuals to perform repairs, adjustments, or alterations to the device or accessories.

Only authorized service personnel may perform repairs, adjustments or alterations on the device and accessories. Any violation will void the manufacturer's warranty. Authorized service technicians are trained and certified only by the manufacturer. The Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions and other information required for service to any Arthrex Authorized Service Center.

5. This device should only be used in compliance with its intended use.
6. Prior to each use, the CCU and all associated equipment must be inspected for proper operation. Visually inspect lenses to ensure there are no scratches, chips or cracks.
7. To carry out safe operation, it is absolutely necessary to carry out proper care and maintenance of the device and accessories. See **"Maintenance"** section of this manual.
8. Ensure that the available mains voltage matches the mains voltage data on the rear of the device which is located near the appliance inlet module.
9. This device may only be connected to endoscopes which, in their intended use and technical specifications, are appropriate for use with the device for the intended medical

procedure. The endoscopes must comply with the latest version of DIN EN 60601-2-18 and ISO 8600.

10. Do not expose the Camera Control Unit (CCU) to moisture, or operate it in a wet area, or store liquids above the CCU.
11. Do not excessively bend or kink instrument power cord or camera head cable.
12. Handle all equipment carefully. If the CCU or camera head is dropped or damaged in any way, return it immediately for service.
13. If the camera head or camera head cable are damaged in any way, or cable or connector jacket are cut, do not autoclave camera head, or immerse camera head in liquid (water, chemical disinfectants or sterilants, etc.). Notify your Arthrex Sales Representative. If it is necessary to return the camera head to Arthrex for service, disinfect the camera head before shipping and reference **"Returning the Device"**.
14. Store camera head and all accessories in a protective container to prevent damage during storage. Do not store CCU where it will be exposed to temperatures in excess of 140°F (+ 60°C).
15. Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above-mentioned requirements. If in doubt, consult your local representative, or the technical department.
16. Any person who connects external equipment to signal input and signal output ports or other connectors has formed a system and is therefore responsible for the system to comply with the requirements of IEC 60601-1. If in doubt, contact a qualified Biomedical technician or your local representative.
17. This equipment has been tested and found to comply with the Class A limits for medical devices to IEC 60601-1-2:. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other device(s) in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
    (a) Reorient or relocate the receiving device.
    (b) Increase the separation between the equipment.
    (c) Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
    (d) Consult the manufacturer or field service technician for help.

    This unit was not evaluated for use with electrosurgical devices which access the site via the same endoscope as the light engine and camera. The unit must be re-evaluated prior to use with electrosurgical devices when they will operate through the same endoscope as the light source and camera.
18. After each use, thoroughly clean unit and accessories (See **"Cleaning, Disinfecting, and Sterilizing"**).

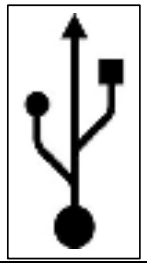
NOTES:

1. Observe all national waste management regulations.
2. Do not dispose of WEEE as unsorted municipal waste.

1.4 Symbol Definitions

- All of the symbols used on the labeling along with the title, description and standard designation number may be found on our website at **www.arthrex.com/symbolsglossary**.

	**Safety Sign** **Follow Operating Instructions**
	**Power Standby/On**
	**ON-OFF** **Push-Push**
	**Attention, Consult Accompanying Documents**
	**Precaution of Warning Notice**
	**Defibrillation Proof Type CF Equipment**
	**Electrical Hazard, Dangerous Voltages are Present. Never attempt to repair the equipment. Only Trained Service Personnel may remove the cover, or obtain access to system components.**

R_x ONLY	**Caution: Federal Law Restricts this device to sale by or on the order of a Physician.**
	**Not for use in the Presence of Flammable Anesthetics.**
	**USB Tablet Computer Connection**
	**Fragile**
	**This Side Up**
	**Keep Dry**
	**Temperature Limits for Storage and Transport**

	**Alternating Current**
	**Protective Earth [Ground]**
	**Equipotential [Equipment Potential]**
	**WEEE [Waste Electronics and Electrical Equipment] Symbol. Regarding European Union End-of-Life of Product.**
	**White Balance Symbol**
	**LED Light**
	**MFi** **Made for iPad**
REF	**Catalog Number**

	**Pressure Limits for Storage and Transport**
	**Humidity Limits for Storage and Transport**
	**Universal Serial Bus**
	**RF Symbol. Non-ionizing Electromagnetic Radiation**
	**Color Video Camera**
	**Do Not Use if Damaged**
EC REP	**EC Rep**
SN	**Serial Number**

1.5 End of Life, Environmental Directives

WEEE Directive [2012/19/EU] on Waste Electrical and Electronic Equipment

The Directive on Waste Electrical and Electronic Equipment obliges manufacturers, importers, and/or distributors of electronic equipment to provide for recycling of the electronic equipment at the end of its useful life.
Do not dispose of WEEE in unsorted municipal waste.
The WEEE symbol on the product or its packaging indicates that this product must not be disposed of with other waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of Waste Electrical and Electronic Equipment. The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your medical endoscopic video equipment at the end of its useful life for recycling, please contact Arthrex Customer Service Department.

The Camera Control Unit (CCU) contains a Lithium Coin BATTERY. The BATTERY must be recycled or disposed of properly.

NOTE for State of California, USA:

State of California Requirement: Lithium Batteries contain Perchlorate Material -special handling may apply. See

www.dtsc.ca.gov/HazardousWaste/Perchlorate

In the US a list of recyclers in your area can be found at www.eiae.org/

1.6 Initial Use of the Device

WARNINGS:

1. **The device is only completely isolated from the mains if the power plug is disconnected from the device's power inlet module. Avoid positioning equipment such that removal of plug is difficult.**
2. **The electrical installation of the operating room where the device is used must comply with applicable national requirements.**
3. **Loss of the Mains Voltage may result in an unacceptable risk due to loss of Clinical Function. An Uninterruptable Power Supply [UPS] is recommended to mitigate this risk.**
4. **The device is not intended for use in areas of explosion hazards. If explosive nitrous gases are used the Camera Control Unit may not be operated in the danger zone.**
5. **Do not simultaneously touch the Camera Control Unit and the patient. Camera Control Unit is intended to be used outside the Patient Vicinity.**
6. **Additional peripheral equipment connected as part of the Endoscopic Video System must meet the requirements of the following specifications:**
   - **IEC 60950 for Information Technology Equipment.**
   - **IEC 60601-2-18 for endoscopic devices.**
   - **IEC 60601-1 for medical electrical equipment.**
7. **All final Endoscopic Video Systems must meet the requirements of IEC 60601-1.**
8. **Whoever connects additional equipment to signal input or signal output is obligated to meet the requirements of the IEC 60601-1 standard.**

CAUTION: Do not install the device in a location near heat sources such as air ducts or radiators and do not expose the device to direct sunlight, excessive dust, or mechanical vibration.

1.7 Unpacking and Inspecting the Device

Upon receipt, carefully unpack the Synergy*UHD4* Camera Control Unit (CCU) and accessories. Ensure contents are complete and are free from damage. If any damage is noted contact your Arthrex Customer Service. Contact the Manufacturer for Return Authorization PRIOR to shipping your device for service. Save **ALL** packaging materials; they may be needed to verify any claims of damage by the shipper.

1.8 Returning the Device

If it becomes necessary to return the device, always use the original packaging. The manufacturer does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging. Please make sure that all required information has been supplied. Call Arthrex for an RMA Number for the device return for service.

- Owner's Name
- Owner's Address
- Owner's Daytime Telephone Number
- Device type and model.
- Serial Number
- Detailed explanation of the damage.

NOTE:

1. The CCU shall be cleaned per section Cleaning, Disinfecting, and Sterilizing prior to returning for service.
2. The Camera Head shall be cleaned and Sterilized per Cleaning, Disinfecting, and Sterilizing prior to returning for service. Camera Head shall be clearly labeled as "Sterile."

Equipment will not be repaired unless decontaminated as stated above prior to return to the manufacturer.

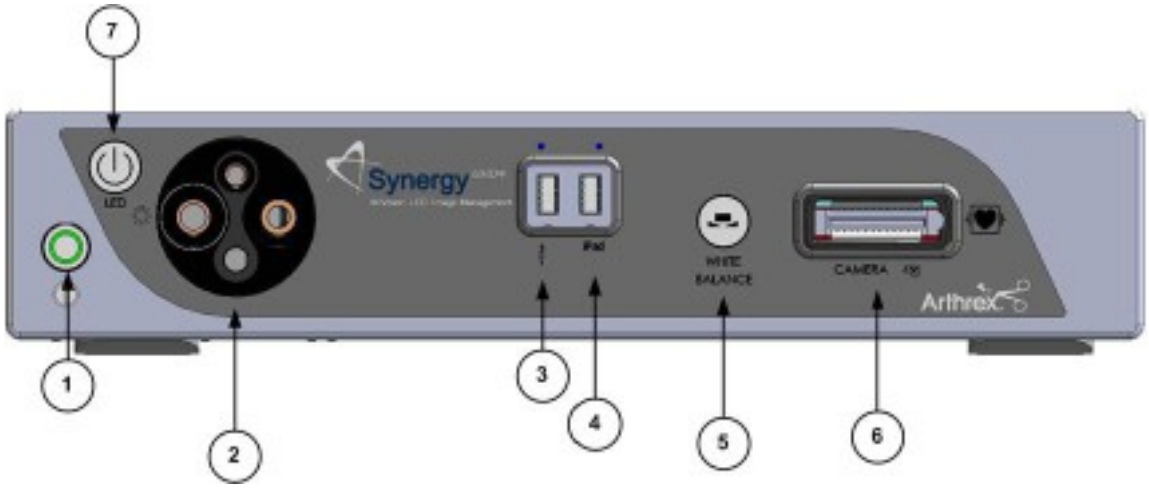


Figure 1- Synergy*UHD4* Front Panel [AR-3200-002X]

1.9 System Indicators

1.9.1 Synergy*UHD4* Front Panel

1. **On/Standby Switch-**The On/Standby switch toggles the Camera Control Unit (CCU) between ON [operational mode] and STANDBY. The Green LED will illuminate when the CCU is in the ON mode. Press and HOLD the switch to toggle between ON and STANDBY.
2. **Light Guide Turret-**Turret for Light Guide input
    - **Wolf Input**
    - **Storz Input**
    - **ACMI Input**
    - **Olympus Input**

    NOTE: Rotate Light Guide Turret until the appropriate port is aligned with LED INDICATOR then Insert Light Guide.

3. **USB Port-**Connect USB devices here.
4. **iPAD USB Port-**Connect iPAD to this port.
5. **"WHITE BALANCE" Button**-Press to initiate camera white balance.
6. **"CAMERA" Input Connection-**Insert the camera head connector here. The camera head connector and receptacle are specially keyed to prevent the camera head from being improperly connected. Ensure that the "UP" label on the camera head connector is facing upwards when the camera head connector is inserted.

    PRECAUTION: Ensure camera head contacts are clean and dry and cooled 15 minutes prior to insertion.

7. **LED Light Engine On/Standby Switch-**The Light Source On/Standby Switch toggles the Light Source between ON [Operational Mode] and STANDBY.

    PRECAUTION:

    Use only FUSED Light Guides to ensure proper operation of LED Light Engine.

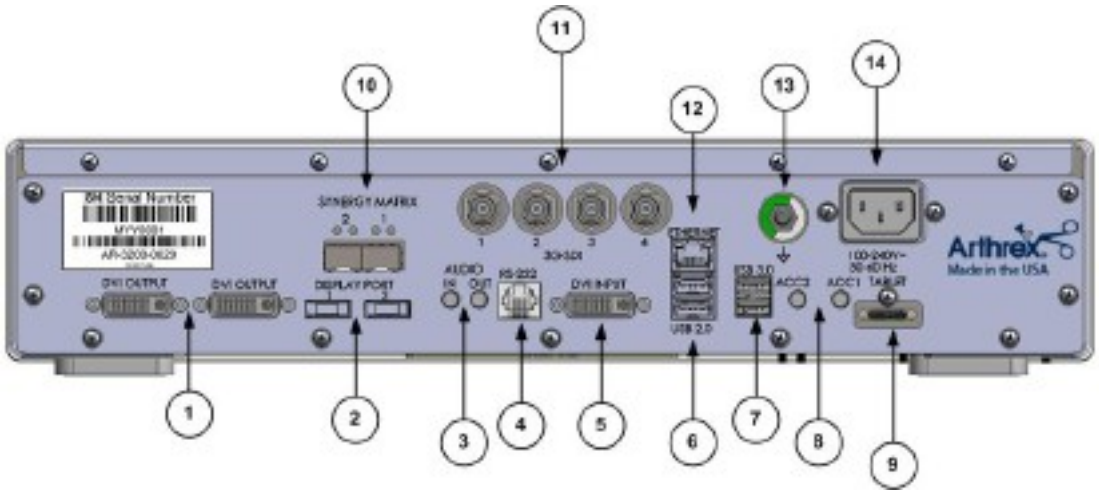


Figure 2- Synergy*UHD4* Rear Panel

1.9.2 Rear Panel

1. **"DVI" Video Output Connectors**-Supplies a digital video signal output in DVI-D format.
2. **Display Ports (2X)-**Supplies UHD Video Signal output in either 1.1 [dual cable] or 1.2 [MST].

   NOTE: Arthrex recommends connecting Synergy*UHD4* to the primary surgical monitor via multiple output types (e.g., display port and DVI, Synergy Matrix and 3G-SDI) in the event that one type of connection is lost.
3. **Audio In / Audio Out-**Audio In: Line Level Audio input for Microphone. Audio Out: Line Level Audio output to Medical Grade Devices.
4. **RS-232 Connector**-Isolated connection to devices requiring Serial Control.
5. **DVI Input-**1080P/60 Input for Picture in Picture [PIP].
6. **USB 2.0 (2X)-**USB 2.0 Connection.
7. **USB 3.0 (2X)-**USB 3.0 Connection.
8. **Accessory Ports (Inputs/Outputs (2X) mini Stereo-Phone Connectors)**-Accessory ports allow for control of the CCU with a footswitch or external device or for the CCU to control external devices via the camera head buttons.
9. **Tablet Connection-**Connection for Tablet Data Input device. Provides for data interchange and tablet charging.
10. **Synergy Matrix [Synergy Matrix Only]-**Fiber Optic output to Matrix Monitor (point to point or managed) via Custom SFP+ Fiber Transceivers. Use Output 1 and 2 for 4K Video. Custom SFP+ Fiber Transceivers and Matrix License may be obtained from Arthrex Customer Service.
11. **3G-SDI Out**-1080P/60 Output.
12. **Ethernet Connector**-Isolated 10/100 Mb/sec.
13. **Potential Equalization Connector (POAG)**-Potential Equalization Connector per DIN 42801.

    NOTE: The purpose of the Potential Equalization Connector is to equalize the potentials between different metal parts of the various Medical Electrical [ME] equipment which make up a Medical Electrical system, or to reduce differences of potential which can occur during operation between the bodies of the Medical Electrical devices and conductive parts of other objects. The Potential Equalization Connector may be connected directly between any ME Devices, or to a common busbar of the electrical installation. Reference IEC 60601-1 for ME Systems.
14. **IEC 320 Power Inlet Module (100-240V~, 50/60 Hz)**-The CCU is equipped with a switching power supply that automatically adjusts to the line voltage being used. Accepts the supplied hospital grade power cord.

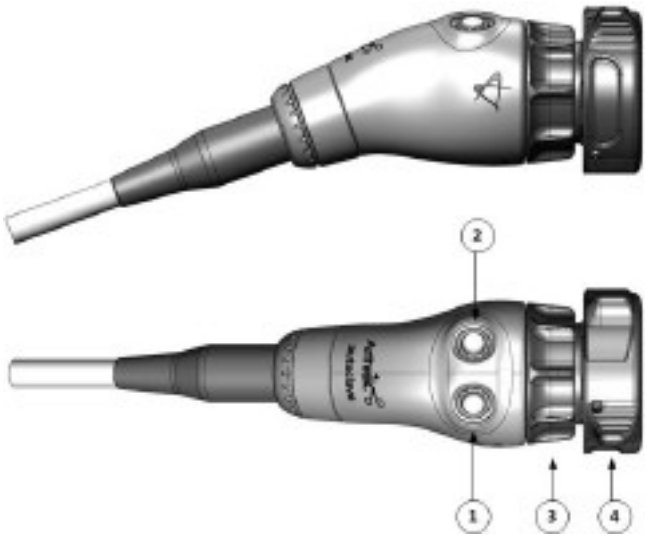


Figure 3- AR-3210-0023 4K Synergy*UHD4* Camera Head, autoclavable

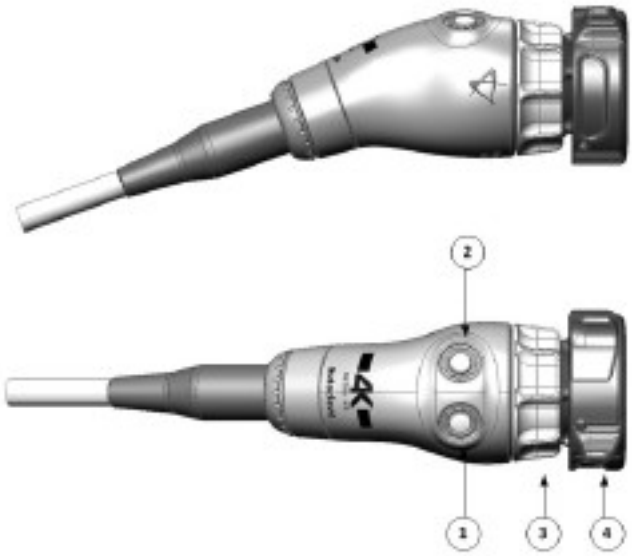


Figure 4- AR-3210-0029 4K Synergy*UHD4* Broadband Camera Head, autoclavable

Figure 5-AR-3210-0018 HD, Synergy*UHD4* Camera Head, autoclavable

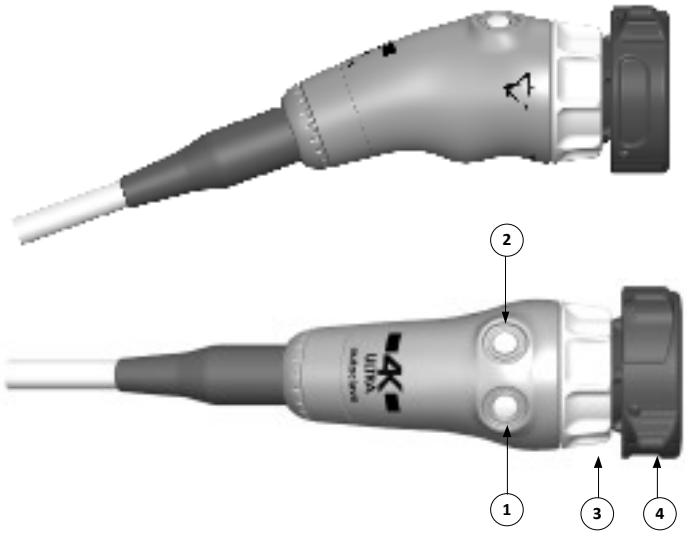


Figure 6-AR-3210-0031 4K Ultra Synergy*UHD4* Camera Head, autoclavable

1.9.3 Camera Heads with Integrated Optics

1. **Button 1**-A programmable button that can activate various functions of the camera. See “Optional Tablet Data Input Device” for programming information.
2. **Button 2**-A programmable button that can activate various functions of the camera. See “Optional Tablet Data Input Device” for programming information.
3. **Focus Ring**-Used to sharpen, or bring into focus, the image detail.
4. **Grasping Mechanism**-Accepts and locks into place the compatible scope. DIN 58105 compliant endoscope interface.

Figure 7-AR-3210-0025 4K Synergy*UHD4* C-Mount Camera Head, autoclavable, AR-3210-0028 4K Synergy*UHD4* C-Mount w/20 foot cable, autoclavable and Not Pictured AR-3210-0026 4K Synergy*UHD4* C-Mount Camera Head, 0 Degree, autoclavable

Figure 8-AR-3210-0030 4K Synergy*UHD4* C-Mount Broadband Camera Head, autoclavable

Figure 9- AR-3210-0021 HD Synergy*UHD4* C-Mount Camera Head, autoclavable, and Not Pictured AR-3210-0022 HD Synergy*UHD4* C-Mount Camera Head, 0 Degree, autoclavable

Figure 10- AR-3210-0032 [4K Ultra Synergy*UHD4* C-Mount Camera Head, autoclavable]

1.9.4 C-Mount Camera Heads

1. **Button 1**-A programmable button that can activate various functions of the camera. See “Optional Tablet Data Input Device” for programming information.
2. **Button 2**-A programmable button that can activate various functions of the camera. See “Optional Tablet Data Input Device” for programming information.
3. **C-Mount Threads**-Accepts standard C-Mount Optical Couplers.

AR-3210-XXXX Camera Head Synergy^{UHD4} Firmware Compatibility

CAUTION:

- **Some AR-3210-XXXX camera heads are only compatible with specific Synergy^{UHD4} firmware versions as shown in the following table. Attempting to use these camera heads with incompatible Synergy^{UHD4} firmware may fail to produce an acceptable quality video output on the surgical display.**

Camera Head	Compatible Synergy^{UHD4} Firmware Version
AR-3210-0029	850-0026-01-A or higher
AR-3210-0030	850-0026-01-A or higher
AR-3210-0031	850-0026-02-B or higher
AR-3210-0032	850-0026-02-B or higher
All other camera head models mentioned in this IFU	All versions

Determining the Firmware Version of the Synergy^{UHD4} System

Firmware can be verified on the **About** screen, which is accessed by double tapping on the open blue area of the home login screen and tapping the About option. The firmware version is listed under Video FPGA as seen in the image below.

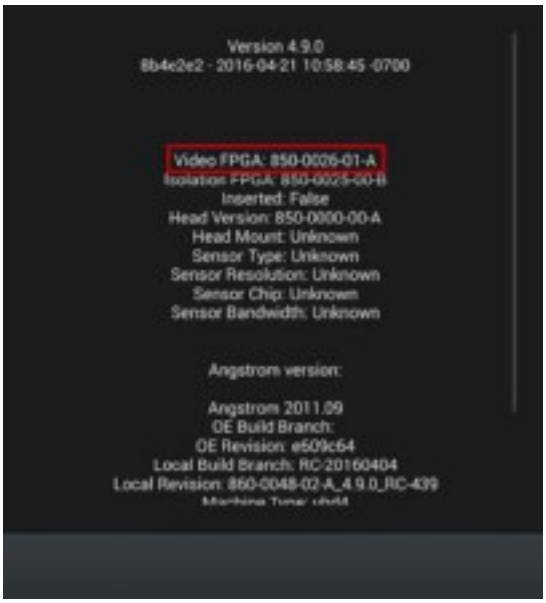


Figure 11- Synergy^{UHD4} Firmware Version

2.0 System Installation and Operation with Data Input Device

2.1 Installation

1. Your Synergy*UHD4* Camera Control Unit will indicate which software configuration is enabled at boot up on the Video Monitor's Splash screen.

2.1.1 Typical System Installation

NOTE: See Typical Interconnect Diagram, Figure 12.

NOTE: Synergy*UHD4* may be installed in a tower or on an equipment boom.

1. Place Synergy*UHD4* Camera Control Unit (CCU) on tower shelf or installed on equipment boom.
2. Attach monitor to the tower or equipment boom and connect monitor DC power cable to the rear panel of the monitor as shown.
3. Attach Synergy*UHD4* Data Input Device to secondary tower arm or equipment boom. Connect the cable from the Data Input Device to the connector labeled "tablet" on the back of the Synergy*UHD4* CCU.
4. Connect a Display Port cable to a Display Port output on the rear panel of the Synergy*UHD4* CCU. Connect the other end of the Display Port cable to the Display Port input of the display monitor. (3G-SDI or DVI cables may be used instead of Display Port cables.) Note: Arthrex recommends connecting Synergy*UHD4* to the primary surgical monitor via multiple output types (e.g., Display Port and DVI, Display Port and 3G-SDI) in the event that one type of connection is lost.
5. If using a printer, connect the printer cable to the USB connector on the rear panel of the Synergy*UHD4* CCU. Connect the other end of printer cable to the printer.
6. Plug the AC power cord into the Synergy*UHD4* power inlet module and a standard grounded AC Mains outlet (100-240 V~, 50-60Hz).
7. Insert the card edge connector of the Synergy*UHD4* camera head into the camera receptacle on the front of the CCU. Ensure the camera had connector contacts are clean and dry prior to insertion.

   WARNING: Inserting an incompatible Camera Head into the camera receptacle (see Figure 1) can result in damage to the CCU.

8. Connect the Light Guide cable into the Light Guide receptacle on the front panel of the Synergy*UHD4* CCU. Attach the other end of the Light Guide cable to the endoscope.
9. Insert the endoscope into the Synergy*UHD4* camera head grasping mechanism or into the C-Mount Coupler for C-Mount Heads.
10. Press the LED Light Engine On/Standby Switch to activate the LED light engine.

    NOTE: If there is no Light Guide cable connected to the Synergy*UHD4* CCU, pressing the On/Standby Switch will not activate the LED light engine until one is connected.

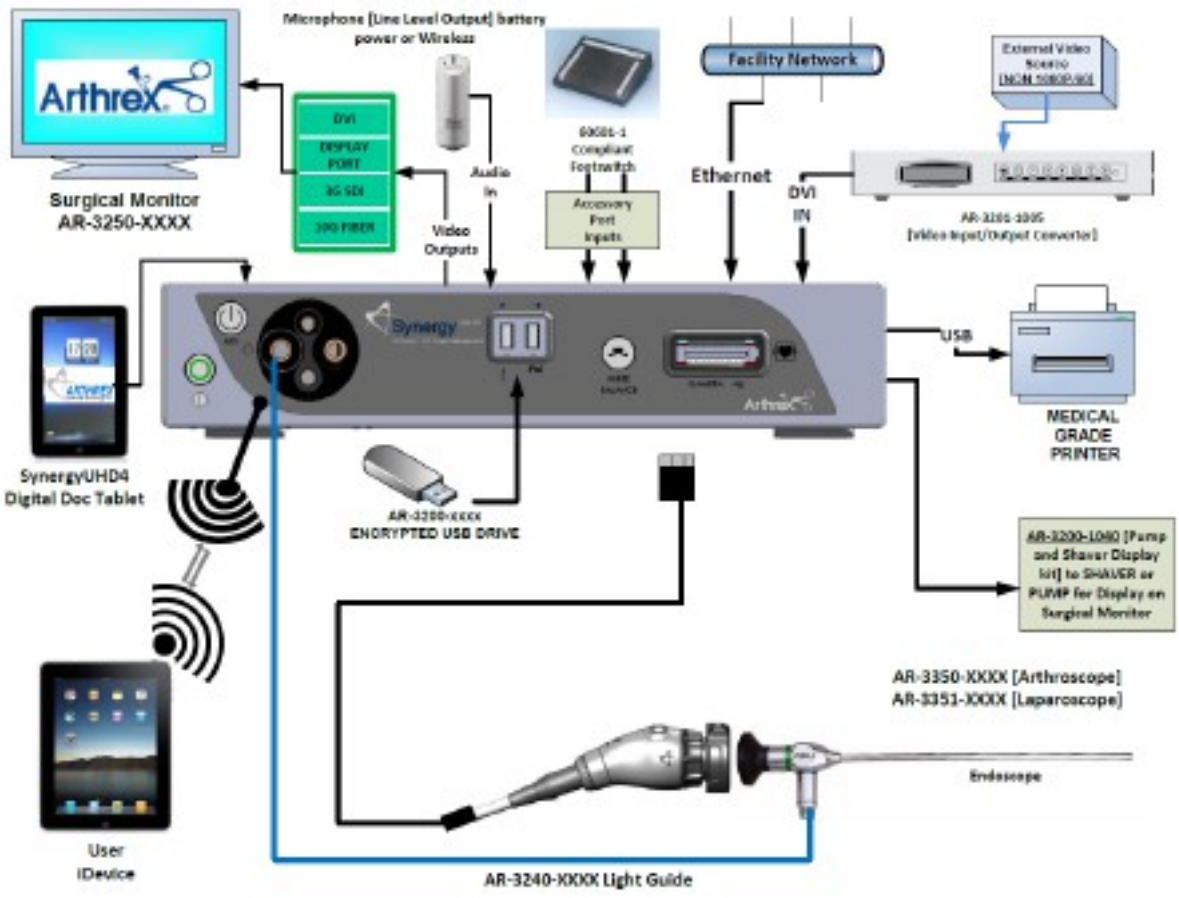


Figure 12- Synergy*UHD4* Typical Interconnect Diagram with OPTIONAL Digital Documentation Tablet [Integrated Optics Heads]

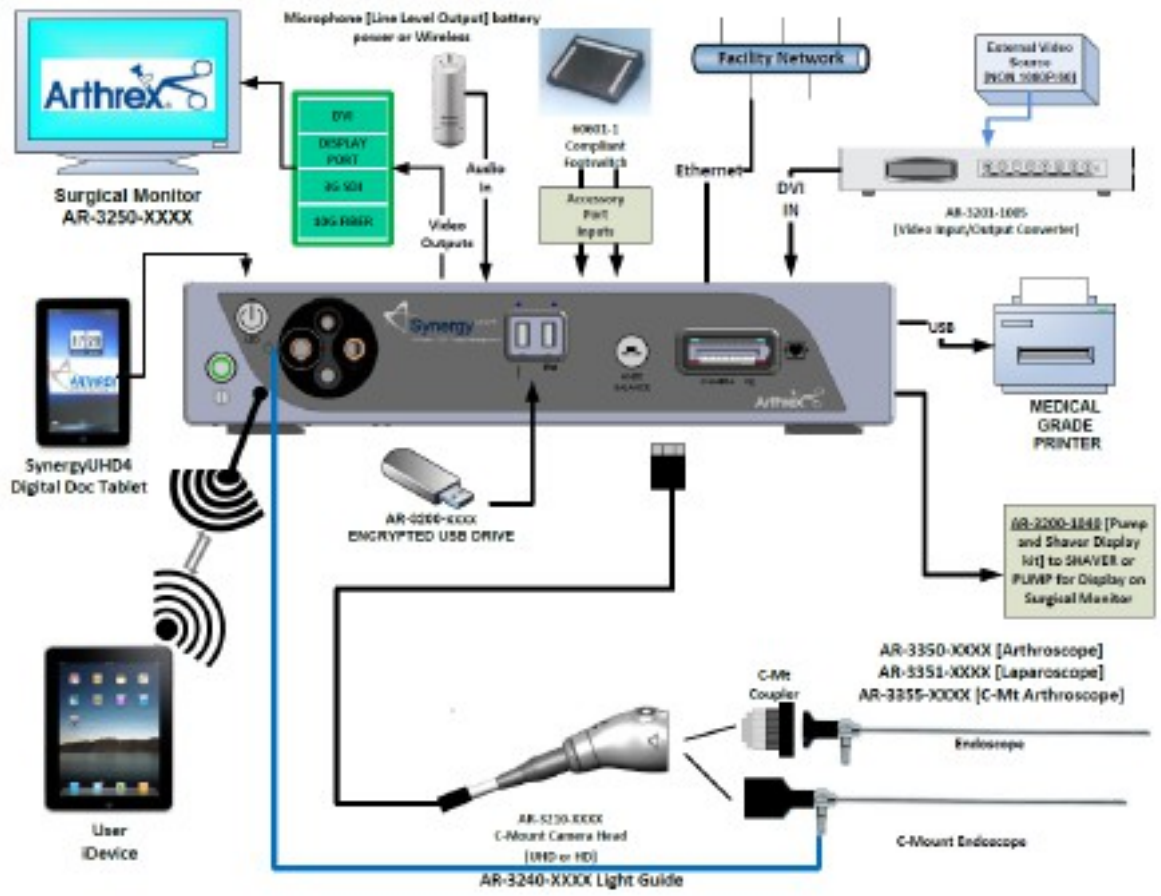


Figure 13- Synergy*UHD4* Typical Interconnect Diagram [C-MT Heads]

2.2 Accessories for Intended Use

Arthrex Synergy*UHD4* System Accessories	
Part Number	**Description**
AR-3250-XXXX	Arthrex Monitors
SONY UP-PR80MD SONY UP-PR80MD with UP-DR80MD/NKIT	Medical Grade Printers
AR-3350-XXXX AR-3351-XXXX AR-3352-XXXX AR-3355-XXXX	Arthrex Arthroscopes Arthrex Laparoscopes Arthrex Hi Mag Laparoscopes Arthrex C-Mount Arthroscopes
AR-3200-1007 AR-3200-1013	Synergy*UHD4* Synergy Documentation Tablet

Arthrex Synergy*UHD4* System Accessories	
Part Number	**Description**
	(AR-3200-1013 must be used with Synergy^{UHD4} *CCU having software version v.4.13.1 or newer.)*
AR-3200-1026, -1027	BioOptico Licenses
AR-3200-1020	DICOM Licenses
AR-3200-1030, -1034, -1036, -1042, -1043, -1044, -1045, -1046, -1047, -1049	Synergy.net Licenses
AR-3210-XXXX	Arthrex C-mount couplers
AR-3200-1010, -1012	Arthrex encrypted USB sticks
AR-3200-1040	Arthrex Synergy System Integration Cable Kit
AR-3370-0006	Arthrex Starfish™
AR-3370-0008	Arthrex C-Mount Starfish
AR-3201-1005	Video Input-Output 1080P Converter
AR-3240-XXXX	Arthrex Light Guides

2.3 System Setup Facility and Surgeon Settings

NOTE: Facility, surgeon, and procedural settings are made from the Synergy*UHD4*'s Tablet Data Input Device. Screens may appear slightly different than those shown in this document depending on the particular features enabled on Synergy*UHD4*.

Figure 14-System Maintenance

2.3.1 System Set-Up can be accessed by pressing the **Maintenance Icon**  on the Synergy*UHD4* Tablet Data Input Device and then selecting **"Advanced Settings"**.

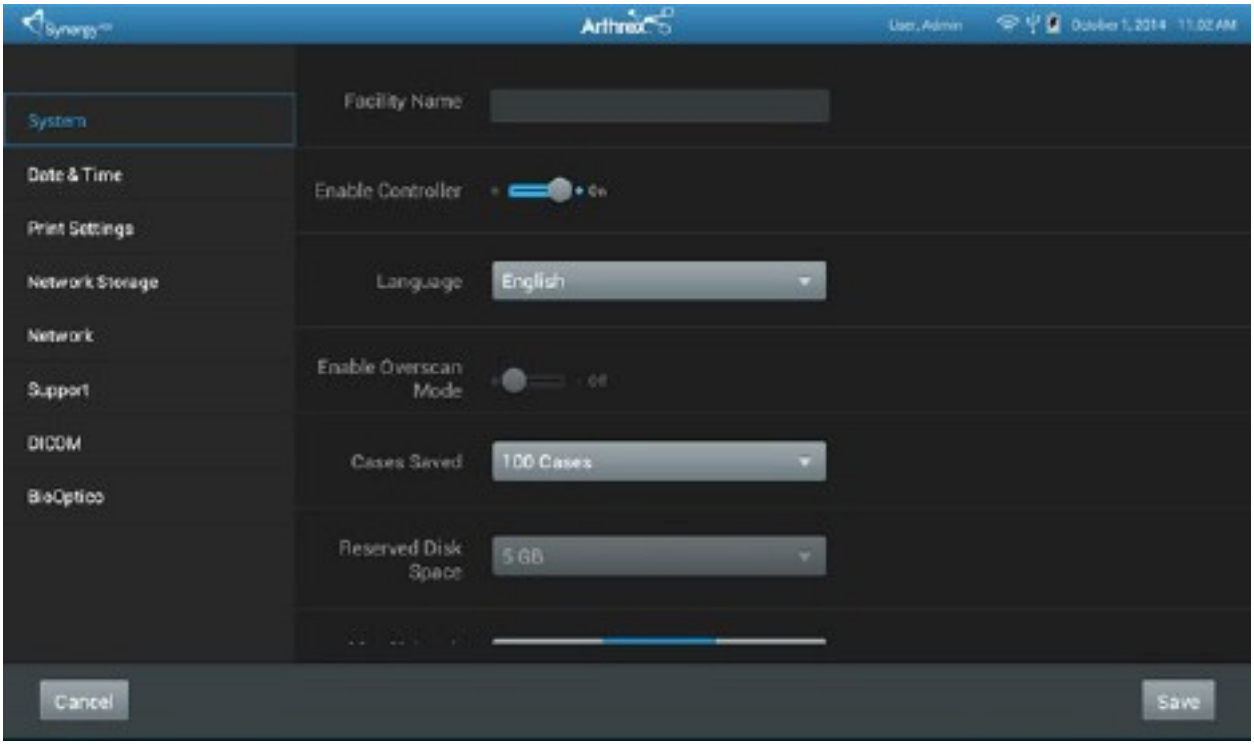


Figure 15-System Maintenance Screen

2.3.2 Selecting "**System**" enables several facility preferences to be setup;

- User can input the facility name associated with that specific Synergy*UHD4*.
- User can select the language used with Synergy*UHD4*.
- User can select number of cases saved to system before data is automatically purged.
- Other configuration options are also available to users.

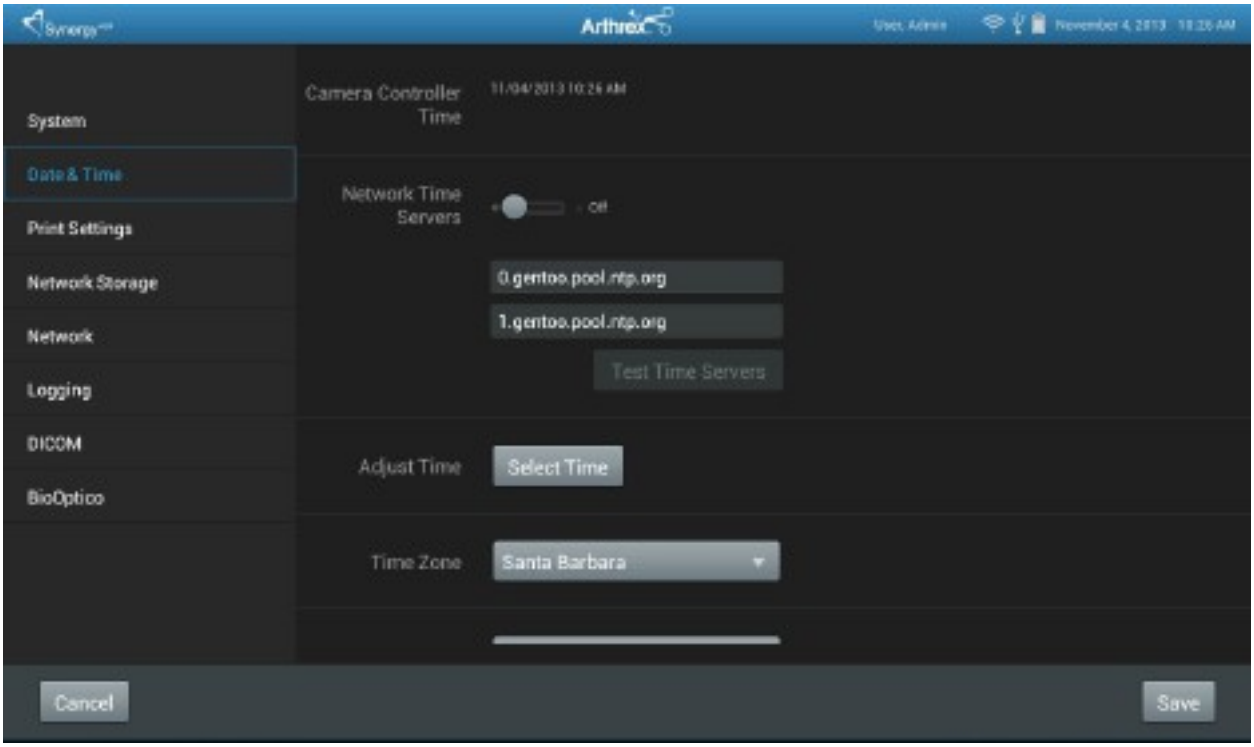


Figure 16-Date & Time Screen

2.3.3 Selecting "**Date & Time**" enables adjustment of the Synergy^{UHD4} date and time settings.

- User can use a network time server or user can select the date and time options manually.

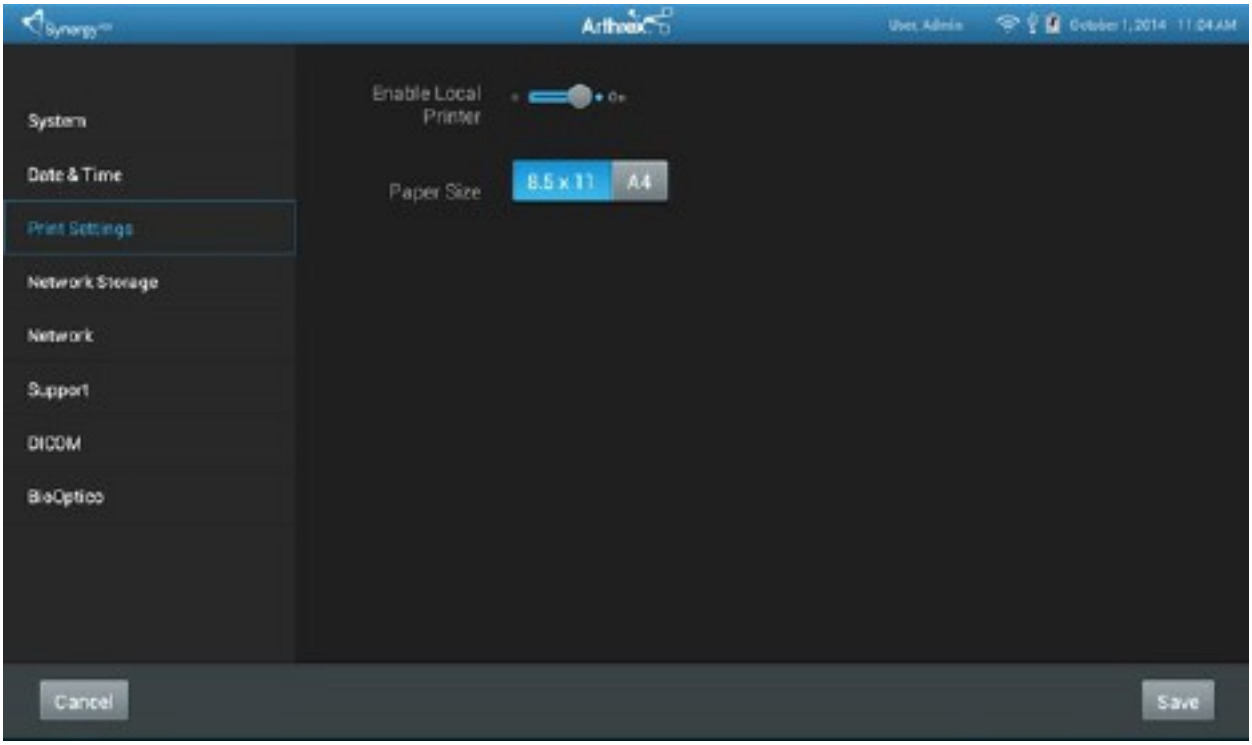


Figure 17-Print Settings Screen

2.3.4 **Selecting "Print Settings" enables adjustment of the Synergy*UHD4* print settings.**

- User can enable the use of a local printer and select the paper size for that printer.

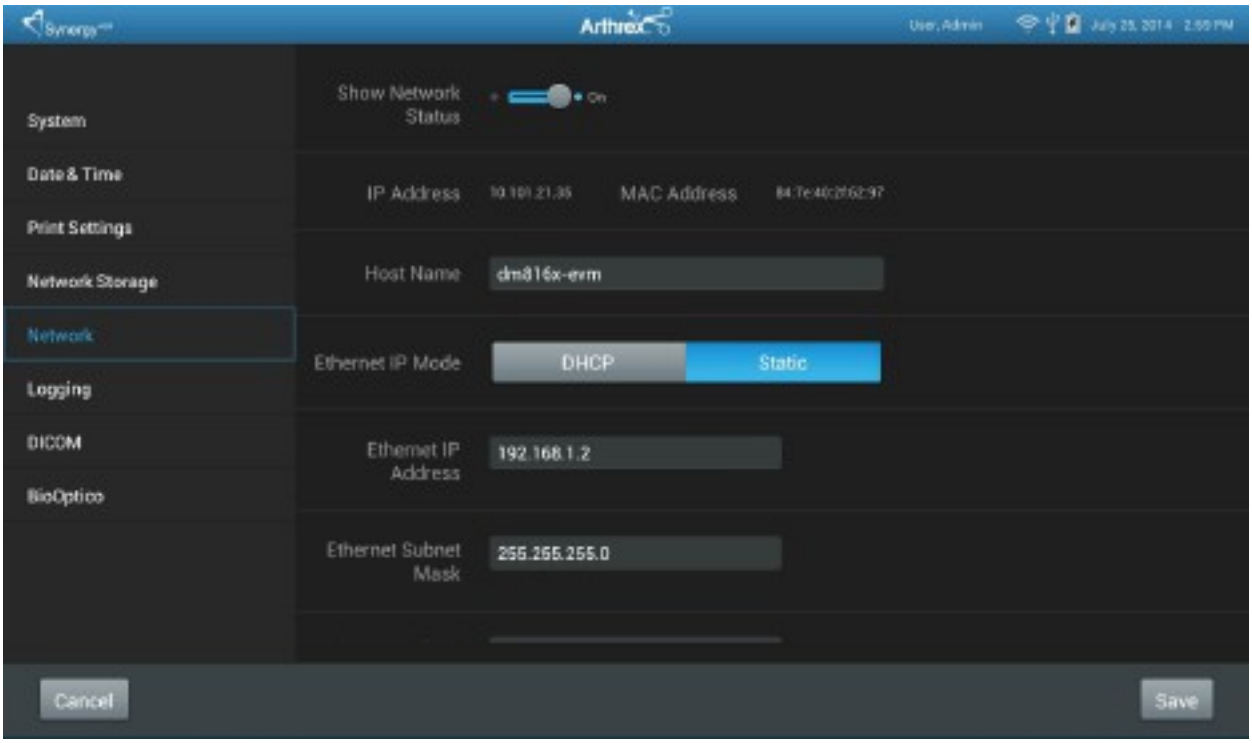


Figure 18-System Maintenance Network

2.3.5 Selecting "**Network**" allows for connecting the Synergy*UHD4* system to a facility network. Fields are:

- Ethernet IP Mode
- Host Name
- Ethernet IP Address
- Ethernet Subnet Mask
- Ethernet Default Gateway

Note: If DHCP option is selected, then the Ethernet address is acquired automatically and no fields need to be completed.

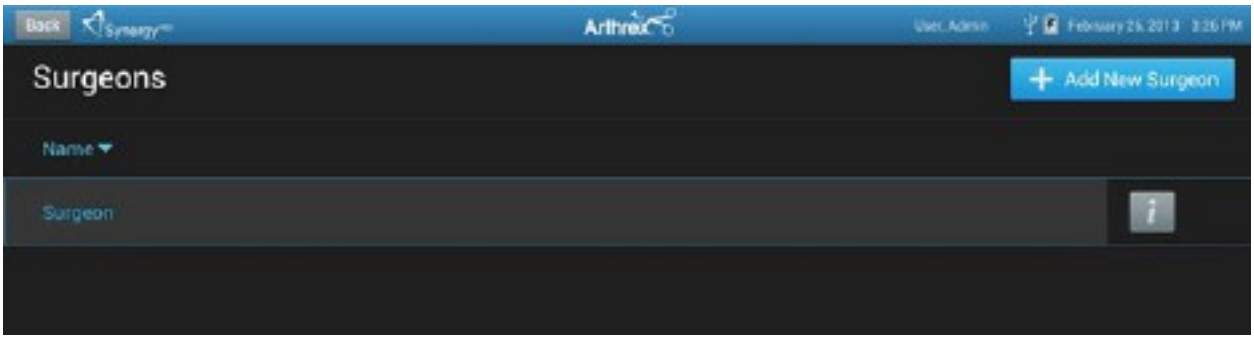


Figure 19-Surgeon Management List

2.3.6 Surgeons can be added to the Synergy*UHD4* with their own system preferences.

2.3.7 To add surgeons and their preferences, press the **maintenance icon**  on the Synergy*UHD4* Tablet Data Input Device and then select **Surgeon Management**. A list of surgeons will appear.

2.3.8 To add a surgeon, press the "+ **Add New Surgeon**" button, enter the first and last name of a surgeon, then press the "**Preferences**" button. Note: When a new surgeon is created it will automatically inherit all of the procedures and preferences associated with the default **Surgeon** account.

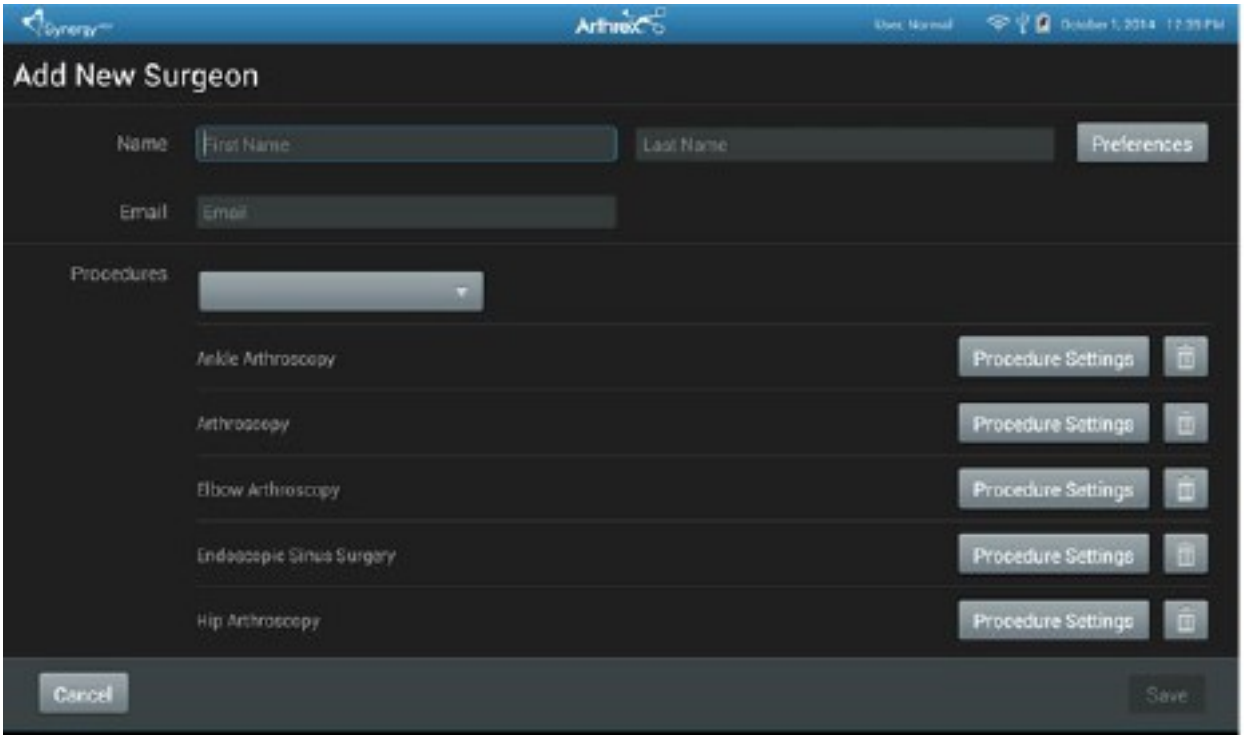


Figure 20-Surgeon Management Preferences

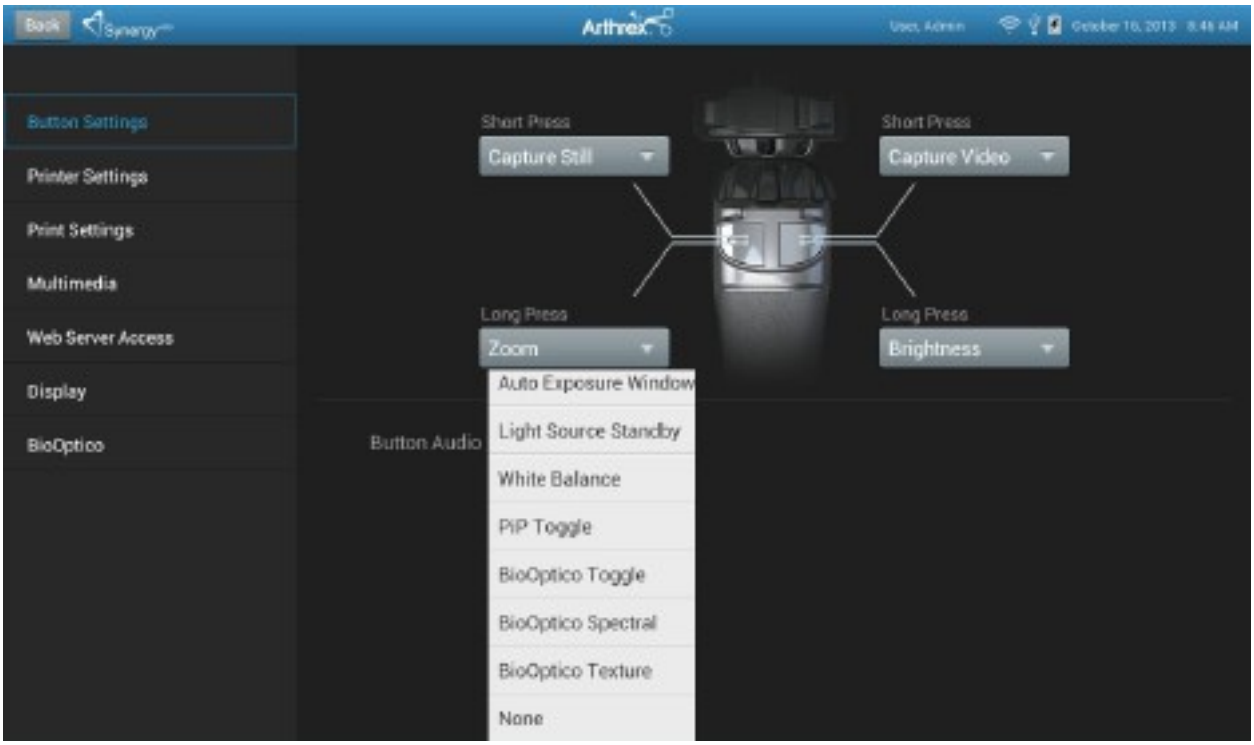


Figure 21-Surgeon Preferences Settings

2.3.9 Surgeon preferences can be defined for the following:

- Camera Button Settings
- Printer Settings
- Print Settings
- Multimedia
- Web Server Access
- Display
- BioOptico (Note: BioOptico is optional functionality for Synergy^{UHD4}.)

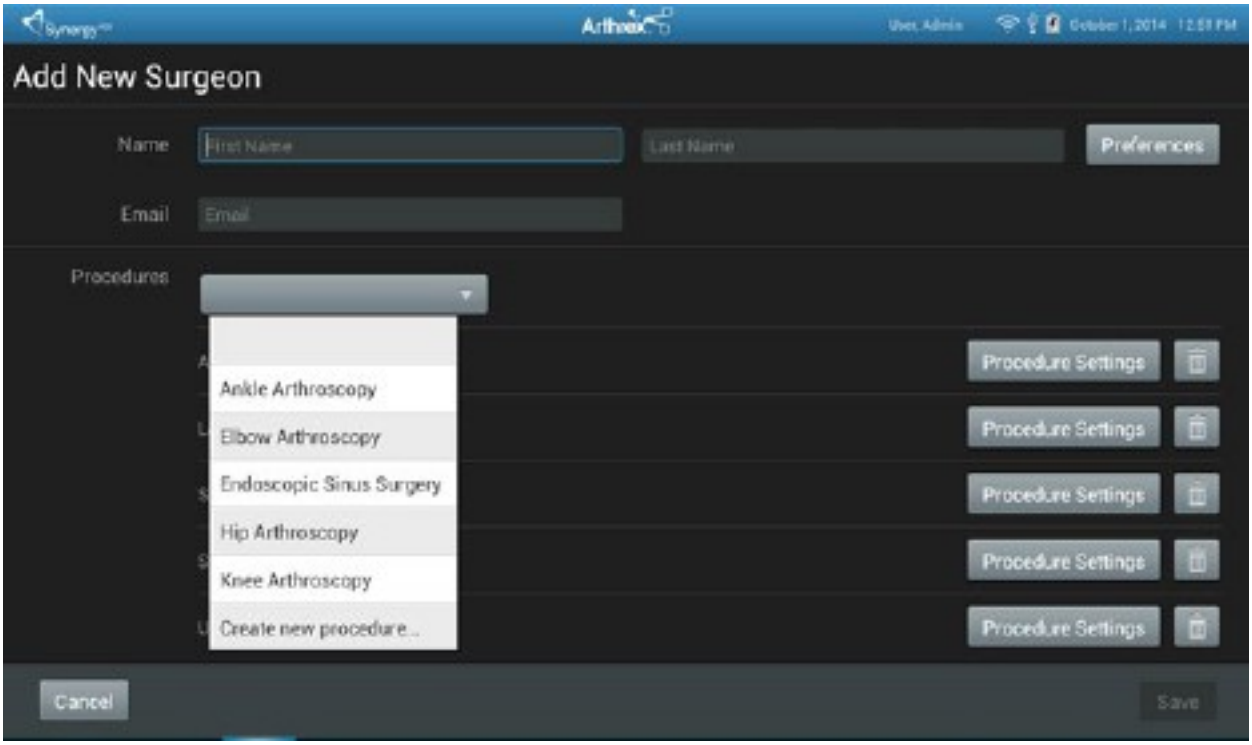


Figure 22-Surgeon Management Procedures Select

2.3.10 Procedure preferences can be added to individual surgeon preferences. On the surgeon management list, **select a surgeon**, and a list of procedures will appear

2.3.11 Select the appropriate Procedure for the Surgeon. If the procedure is not currently in the list, select the "**Create New Procedure**" from the Procedures drop down list, and enter the name of the new procedure.

Figure 23-Surgeon Procedure Settings

2.3.12 Once a Procedure has been added select the "**Procedure Settings**" next to the Procedure name to configure camera, pump, and shaver settings associated with the Procedure.

2.4 Icon Guide

2.4.1 Figure 24 shows what is displayed on a surgical monitor when a Synergy^{UHD4} is first powered on.

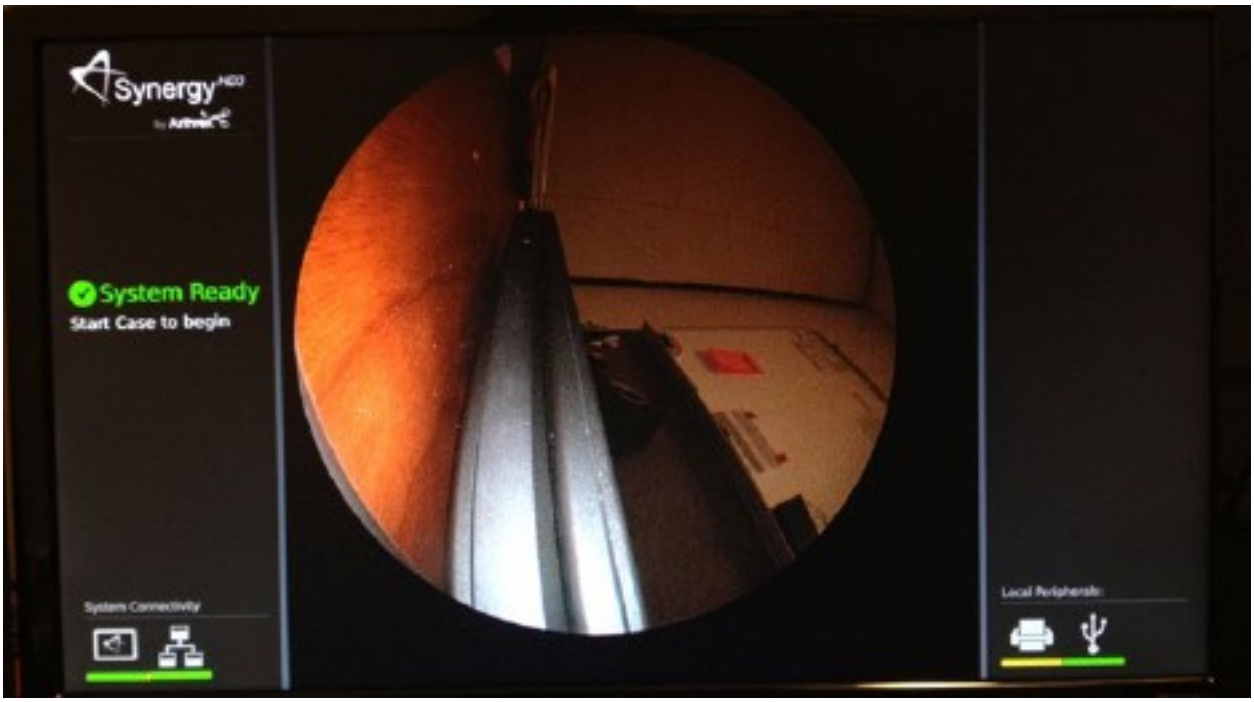


Figure 24-Connectivity Icons

2.4.2 In the lower left corner of the screen are icons that represent connectivity with Synergy^{UHD4}. The icons shown below represent tablet, network, and Synergy.net connectivity.

2.4.3 The icons on the lower right of the monitor represent local and external peripheral connectivity (e.g., printer, USB, iPad, DICOM, network export) as shown in the figures below.

Printer USB iPad DICOM Network Synergy.net

2.4.4 Beneath each of the icons is a status bar. The color of the bar indicates the status of the connection. A status bar that is green means that there is active connectivity between that device and Synergy*UHD4* and no issues are detected. A status bar that is blue means that there is active connectivity between that device and Synergy*UHD4*, no issues are detected, and an active data transfer is taking place (e.g., images are exporting to a USB device or a DICOM export is ongoing). At the end of a data transfer, the blue status icon will change back to green. A status bar that is yellow means that connectivity should be present but there is an issue with the connection. A status bar that is gray means that the device is not connected to Synergy*UHD4*.

2.4.5 A yellow status bar event should be investigated prior to the start of a case as data transfers may not occur to any device where connectivity with Synergy*UHD4* has not been established or has been lost.

2.4.6 Once a case is started, a smaller subset of connectivity icons will appear in the lower right corner of the surgical monitor. These status icons represent connectivity status based on the individual surgeon's preferences (e.g., if a surgeon has autoprinting enabled but the printer is powered off it will show a yellow status). The colors of the status bars match those described above. Again, any items with a yellow status should be investigated for issues prior to the start of a case.

2.4.7 The onscreen status icons are intended to only provide a status of connectivity of various devices to Synergy*UHD4*. A surgeon can always begin and perform a case regardless of the status of any of the device connections.

2.5 Scheduling and Starting Cases

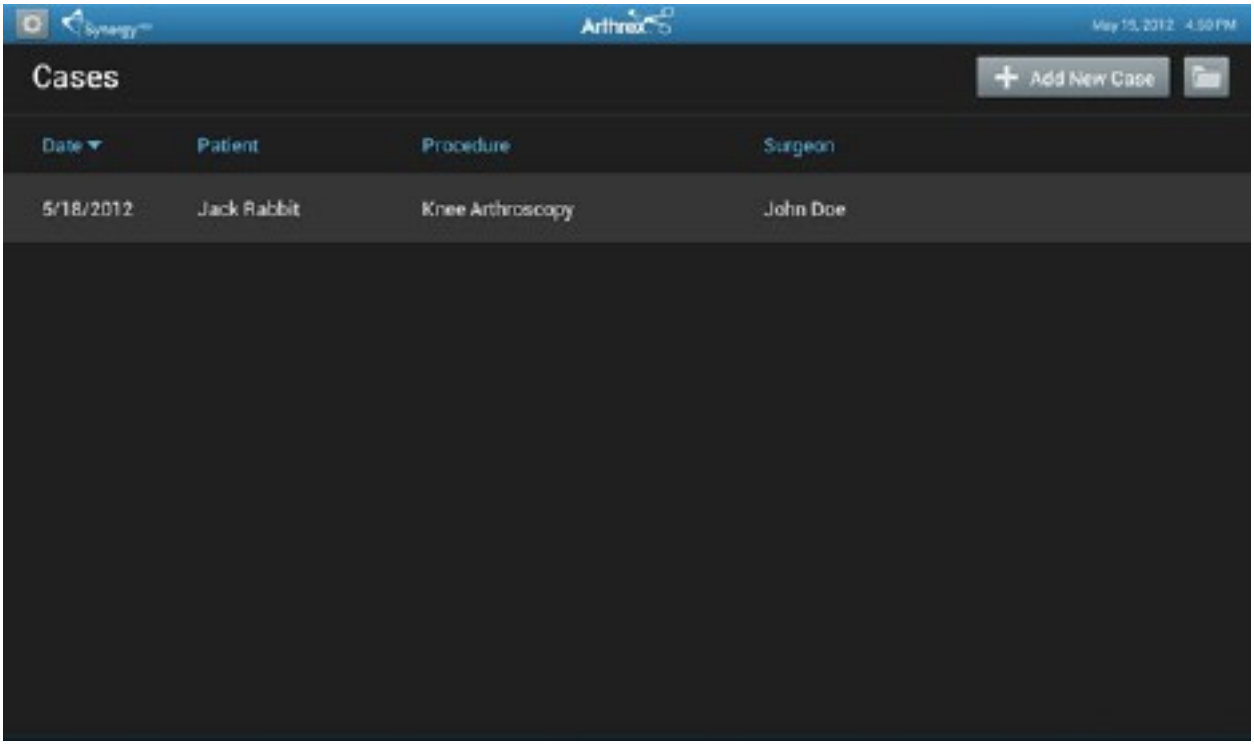


Figure 25-Scheduling a Case

2.5.1 To schedule a case, press the **"+ Add New Case**" icon.

Figure 26-Scheduling a Case

2.5.2 Select the "**Room**" (if present, optional field depending on how system is configured), "**Surgeon**" and/or "**Procedure**," and enter data in the following required fields.

- Patient First Name
- Patient Last Name
- Patient I.D. #

2.5.3 Input any of the other optional data elements in the appropriate fields.

2.5.4 Press the "**Save**" icon.

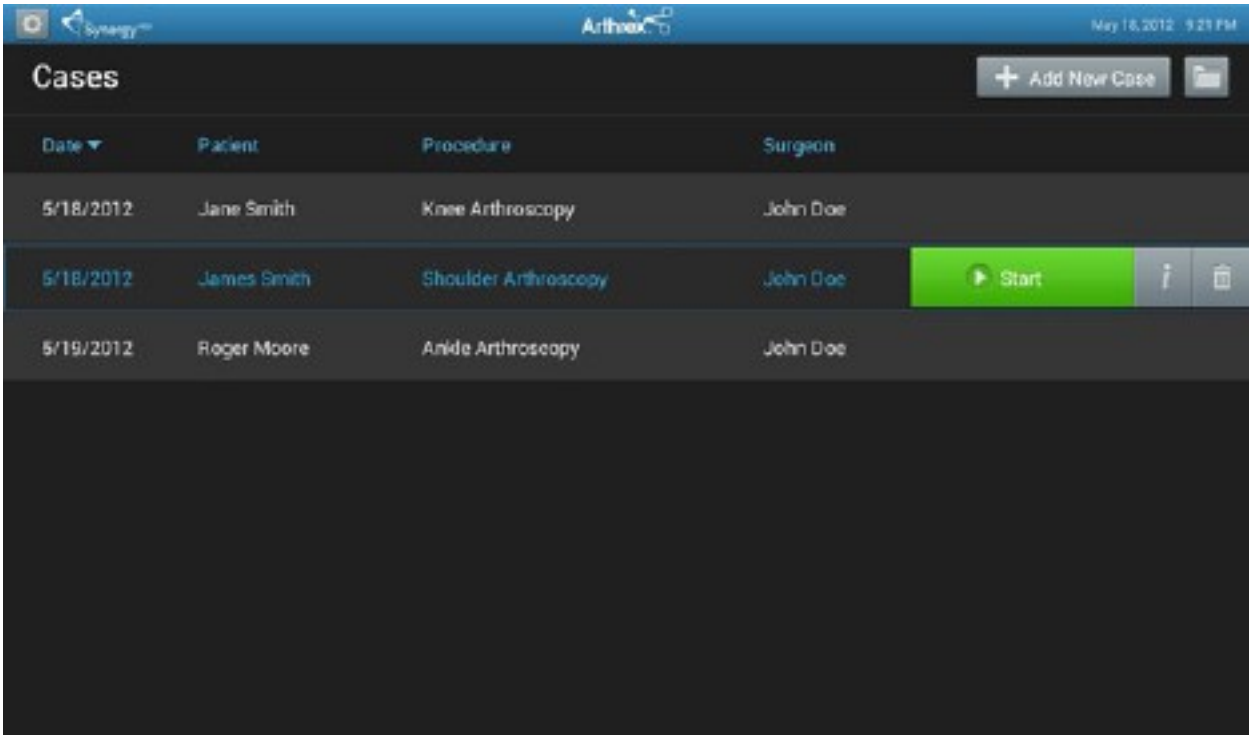


Figure 27-Starting a Case

2.5.5 To start a case, select the case/patient from the Case List and press the "**Start**" icon.

NOTE: Cases may also be started from the "**Add Case**" screen by entering the required fields and pressing the "**Start**" icon.

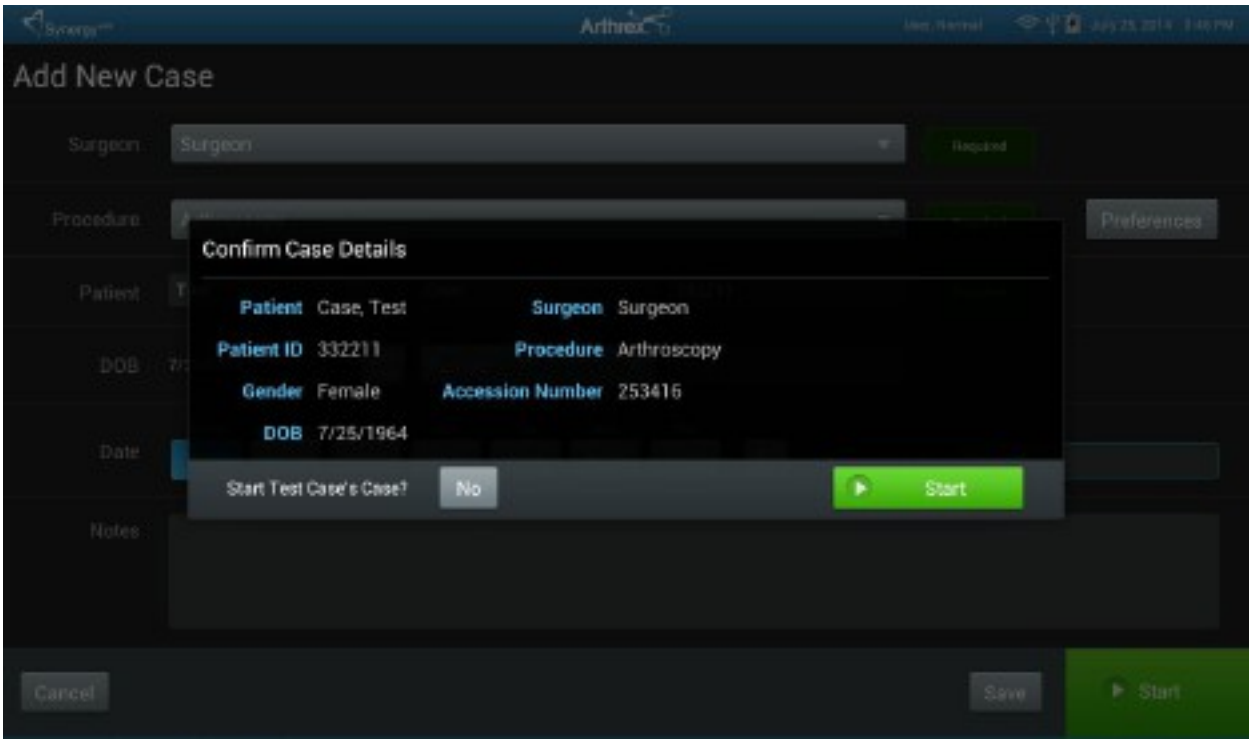


Figure 28 -Confirming a Case

2.5.6 A "**Case Confirmation**" window will appear showing the patient and case demographics. If the information is correct press the "**Start**" icon.

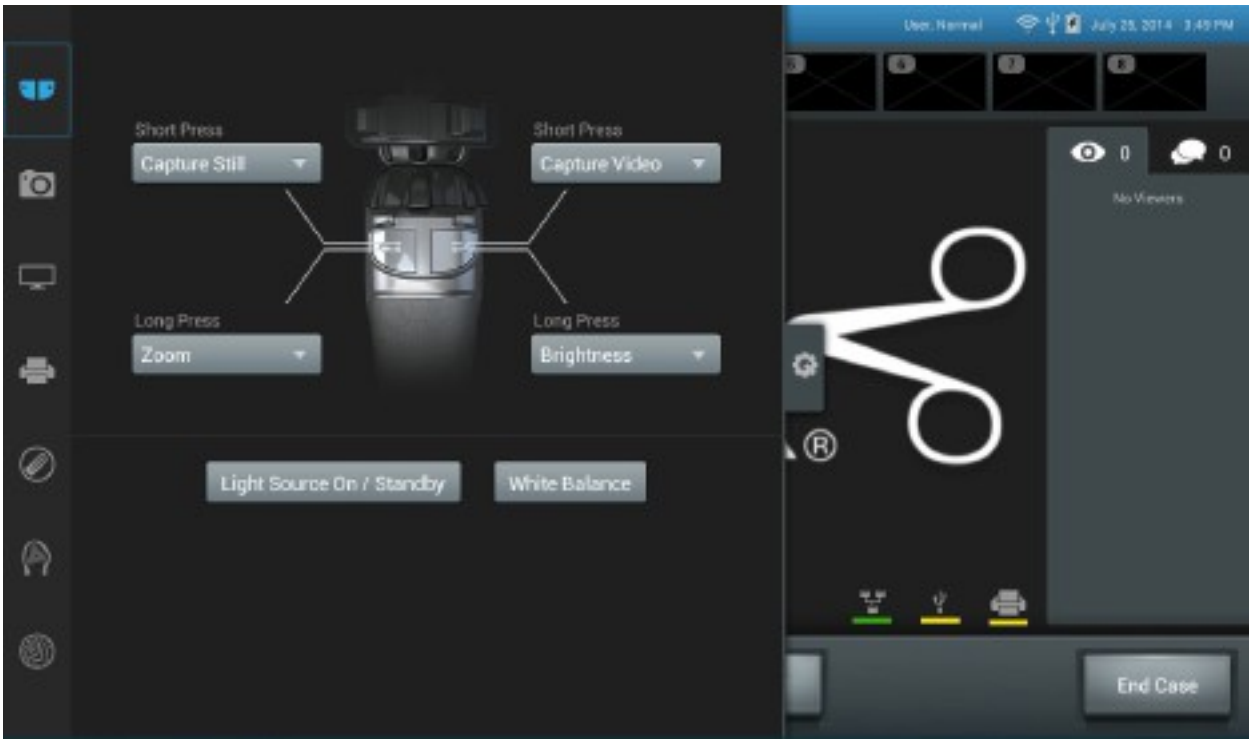


Figure 29 -Camera Head Button Change During Case

2.5.7 Changes to SETTINGS may be made during the procedure by pressing the **"Maintenance Icon**". Changes may be made to the following:

- Camera Head Button Functions
- Print Settings

Figure 30 -Print Changes During Case

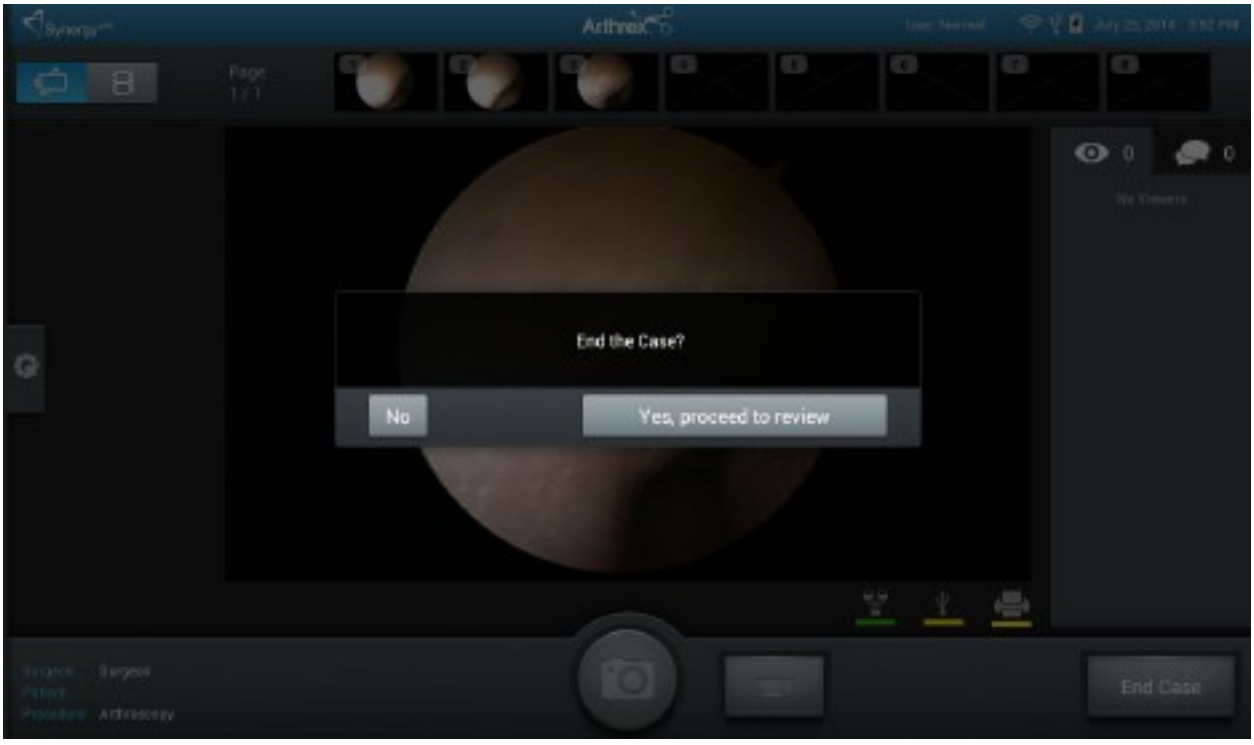


Figure 31 -Ending a Case

2.5.8 Ending a Case; to end a case, press the "**End Case**" Icon.

NOTE: An "End the Case?" confirmation message will appear. If confirmed, the case will end, and the Synergy^{UHD4} Tablet Data Input Device will transition to the case review screen.

2.6 Status Notification Icons

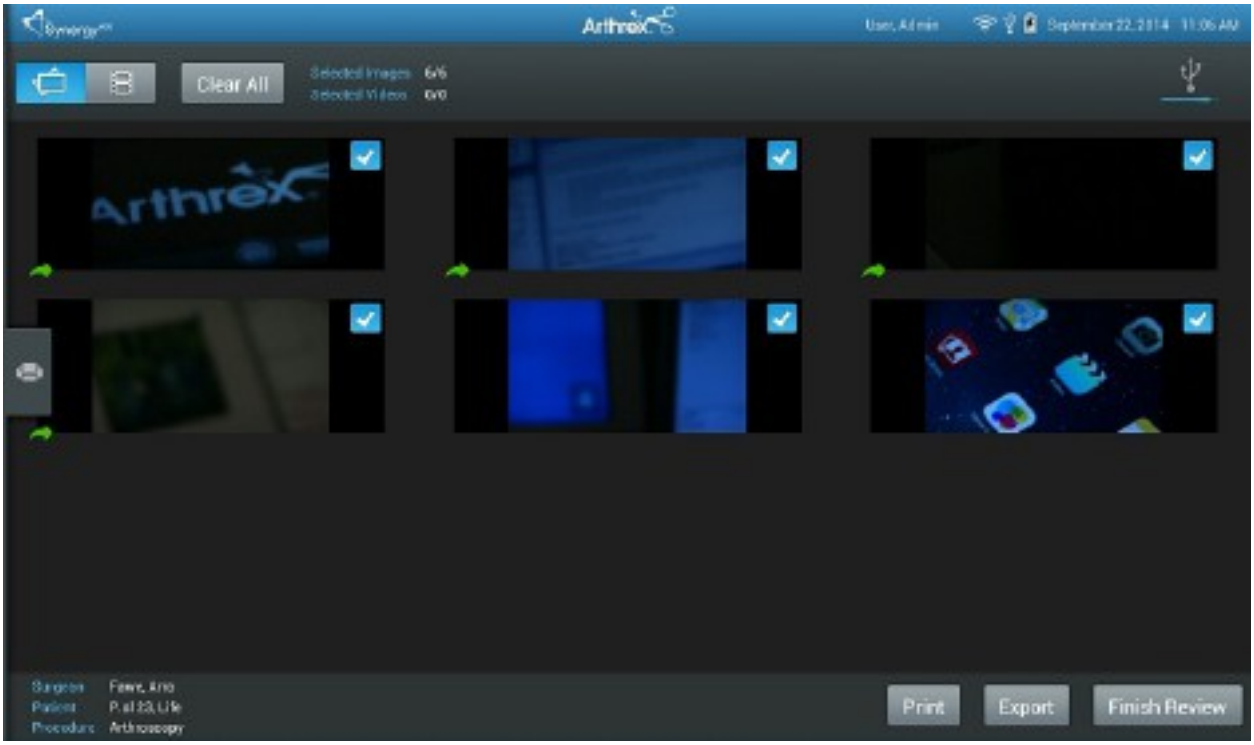


Figure 32 -Status Notification Icons

2.6.1 When a manual export/print is performed, the status notification for the action will appear on the tablet. The blue progression bar will indicate that the export is in progress. Once the export is complete the status bar will turn green. Green arrows for each image indicate a successful export.

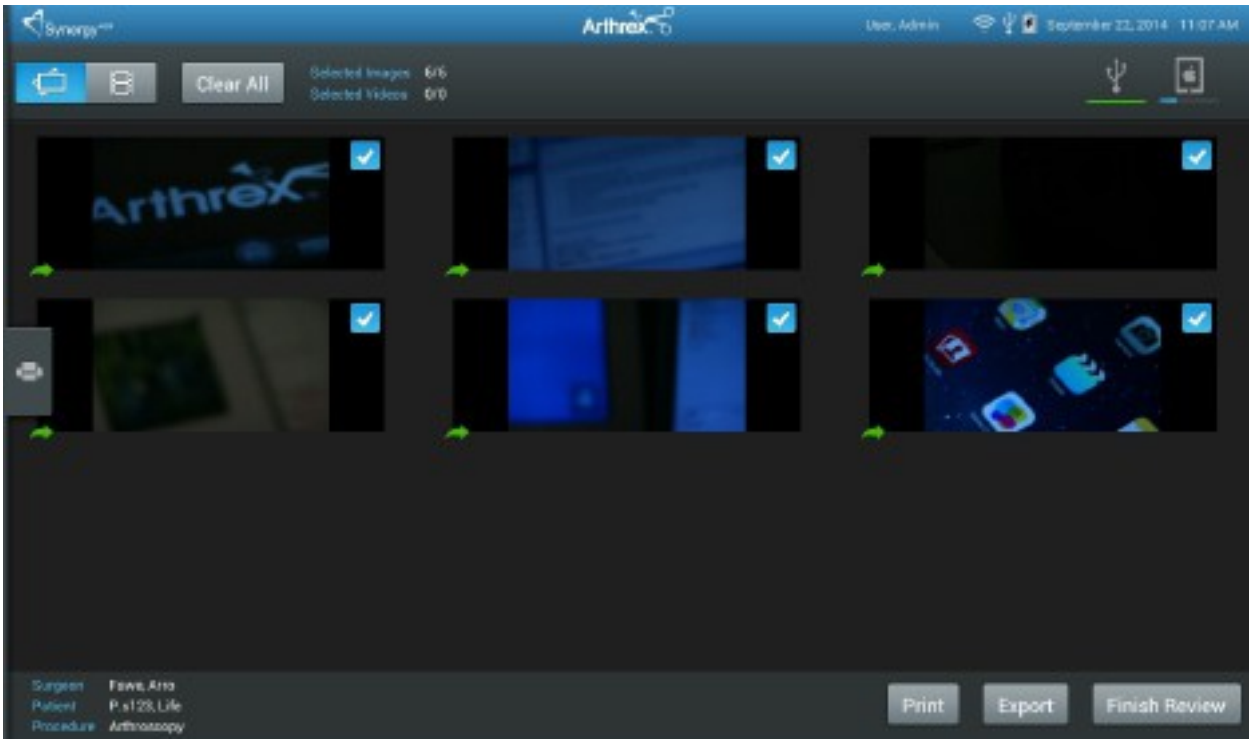


Figure 33 -Export Status

2.6.2 The system in Figure 33 displays a successful USB export and an iPad export in progress.

Figure 34 -Export and Print Status During a Case

2.6.3 Export and print statuses will also display during surgery if auto export or auto print is enabled for the surgeon using the system. A successful export will display a green checkmark for the images completed. A failure will be displayed by a yellow caution triangle. (Note: Print statuses are not reflected in the individual image status icons.) The external devices statuses and connectivity status will also be displayed during the case in the lower right corner of the tablet.

2.7 System Operation without Tablet Data Input Device

1. Connect the Synergy*UHD4* System per “Typical System Installation”, Figure 12 and Figure 13.
2. The camera will take approximately 60 seconds to fully load its boot software. When the software has fully loaded, you will see the Synergy*UHD4* Initial Screen shown below in Figure 35.

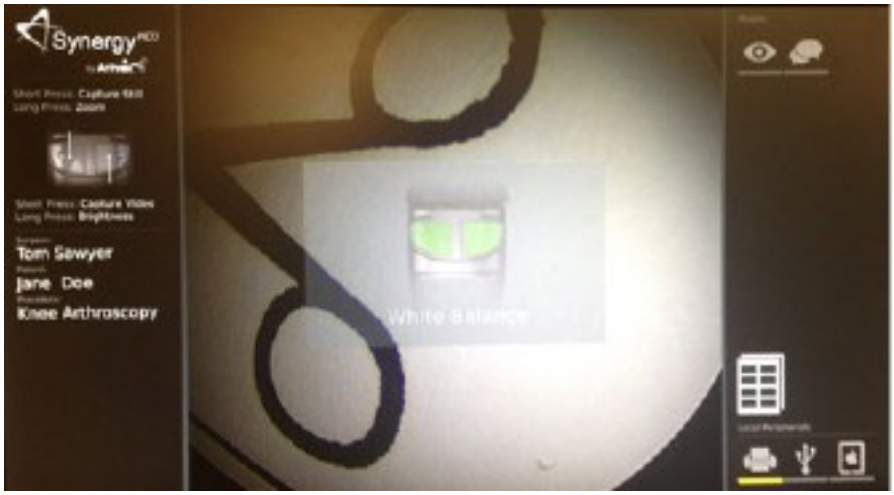


Figure 35 -Synergy*UHD4* Initial Screen

3. The Synergy*UHD4* Initial Screen will indicate the Factory Default settings for the Camera Head Button programming.
4. SHORT presses on both buttons will capture Still Images.
5. Long Press on the LEFT BUTTON will control Brightness.
   - After a LONG press on the LEFT BUTTON, pressing the Right Button will INCREASE Brightness.
   - After a LONG press on the LEFT BUTTON, pressing the Left Button will DECREASE Brightness.
6. Long Press on the RIGHT BUTTON will control Digital Zoom.
   - After a LONG PRESS on the RIGHT BUTTON, pressing the RIGHT Button will INCREASE ZOOM.
   - After a LONG PRESS on the RIGHT BUTTON, pressing the LEFT Button will DECREASE ZOOM.
7. The Synergy*UHD4* Initial Screen will also indicate that the Printer is Active and that it is set to 8 prints per page.
8. The center screen of the Synergy*UHD4* Initial Screen shows that both Buttons are now set to White Balance, and that a White Balance Operation is required to initialize the Synergy*UHD4* use.
9. Turn on the LED Light Engine.
10. Using a stack of 4 x 4 white gauze, hold the tip of the Endoscope approximately 1 inch (2.5 cm) away from the gauze until the gauze image fills the screen completely.
11. Press either of the Camera Head buttons to start the White Balance Operation.
12. The Surgical monitor will display one of the following.
    - When the White Balance has been completed successfully, a Green Check Mark with WHITE BALANCE below will be shown on screen.

Figure 36 -White Balance OK

- When the White Balance has not been completed successfully, a Red X with WHITE BALANCE below will be shown on screen.

Figure 37 -White Balance Fail

13. If the White Balance Operation has been successful, the camera will enter the Surgical Ready Mode and be ready for surgical operation.
14. If the White Balance Operation has not been successful, you must move the Tip of the Endoscope closer or farther from the White Gauze until the operation can be completed successfully.
15. Once the White Balance Operation has been successfully completed, the Camera Head buttons will function as defined on the Synergy*UHD4* Initial Screen Figure 35.

3.0 Maintenance

Regular and proper maintenance of your Synergy*UHD4* and/or AR-3210 Camera Heads are the best ways to protect your investment and avoid non-warranty repairs.

Recommended care and handling of the Synergy*UHD4* Camera Control Unit (CCU) and camera head includes proper day-to-day operation, cleaning, and sterilization which are extremely important to ensure safe and efficient operation. It is important to visually inspect the camera head, cable and card edge before each use.

Your authorized Arthrex service department is the most knowledgeable about the Arthrex Medical Camera Systems and/or camera heads and will provide competent and efficient service. Any services and/or repairs done by any unauthorized repair facility may result in reduced performance of the instruments or instrument failure.

3.1 Life Expectancy

Life expectancy for the product is expected to meet and exceed the warranty period for approximately 5 years under normal use and standard of care.

3.2 Periodic Maintenance

The product should be inspected prior to and after each use to ensure that the camera head, cable, strain relief, overmold, or connector contacts are not damaged or worn. If it becomes necessary to return the camera head to Arthrex for service, please sterilize the camera head before shipping.

3.3 Cleaning, Disinfecting, and Sterilizing

Follow universal precautions for protective apparel when handling and cleaning contaminated instruments.

3.3.1 Cleaning the LED Light Engine

1. Allow LED Light Engine to cool for ½ hour before cleaning.
2. Dampen one end of a cotton swab with isopropyl alcohol.
3. Clean any residue from optic using circular motion.
4. Use the DRY END of the cotton swab to dry the face of the optics.
5. Inspect the optics for residue or cotton fibers and clean as required.
6. Allow to AIR DRY for 5 minutes prior to use.

3.3.2 Cleaning and Disinfecting the Camera Control Unit (CCU) and Tablet

1. Turn the CCU power off. Disconnect the power cord from the electrical power source and from the rear of the CCU.
2. Remove the camera head from the CCU.
3. Wipe the CCU with a disinfecting towelette or clean, low-linting cloth dampened with disinfectant solution.
4. Using a second (fresh) towelette or cloth, thoroughly wet the surface and ensure it remains visibly wet for the contact time recommended by the disinfectant manufacturer. The use of additional towelettes or cloths may be used to ensure the surface remains visibly wet for the entire contact time.
5. If required by the disinfectant manufacturer, rinse per instructions; otherwise, allow to air dry.

CAUTION: Do not sterilize the CCU/Tablet or immerse in liquid or disinfectant solution.

CAUTION: Do not clean the CCU/Tablet with abrasive cleaning or disinfectant compounds, solvent, or other materials that could scratch or damage the device.

Always comply with the instructions issued by the manufacturer of the cleaning disinfectant regarding concentration, exposure times, temperature, and material compatibility.

3.3.3 Cleaning the Camera Head

CAUTIONS:

- **If the camera head is dented or damaged, or if the cable silicone jacket is cut, DO NOT autoclave or immerse in liquid (water, chemical disinfectants or sterilants, etc.). Notify your Arthrex Sales Representative.**
- **Do not place the camera head or accessories in an ultrasonic cleaner or ultrasonic washer-disinfector.**

Devices must be adequately cleaned and sterilized prior to use or re-use. All devices are to be cleaned and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile devices. Effective cleaning is an indispensable requirement for an effective sterilization of the devices.
If possible, the Automated Cleaning procedure (Washer-Disinfector) should be used for cleaning. The Manual Cleaning procedure should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of the manual procedure should be considered. Manual cleaning may require onsite validation by the healthcare facility and appropriate procedures should be in place to avoid human factor variability.

3.3.3.1 Point of Use Preparation, Containment, and Transportation

It is recommended that camera heads are reprocessed within a maximum of 2 hours of use. At point of use, soiled devices must be removed from trays and moistened to prevent debris from drying before transportation to the reprocessing area for cleaning procedures. Soaking in enzyme solutions facilitates cleaning, especially in devices with complex features and hard-to-reach areas (lumens, etc.). These enzyme solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on devices. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed. Devices should be contained and transported in a closed, puncture-proof device to ensure safety.

3.3.3.2 Detergent Selection

Consider the following points during selection of the cleaning detergent:

1. Suitability of the cleaning agent for cleaning (no foam development).

2. Compatibility of the cleaning agent with the devices. Arthrex recommends the use of neutral pH or enzymatic cleaning agents. Alkaline agents may be used to clean devices in countries where required by law or local ordinance, or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) or Creutzfeldt - Jakob disease (CJD) are a concern (applies only outside of the US). Arthrex does not recommend the use of a specific brand of cleaning agent. Enzol® and neodisher® MediClean forte were utilized during the validation of these instructions. **Caution: Low acid or alkaline solutions are not recommended, as they corrode metal parts and compromise plastics.**

Follow the instructions of the detergent manufacturer regarding use concentration and temperature for either manual or automated cleaning. Please use only freshly prepared solutions as well as only purified (critical, e.g. RO or DI) water for final rinse.

3.3.3.3 Automated Cleaning

1. Load the devices in the washer-disinfector such that all design features of the device are accessible to cleaning.
2. Make sure that the camera head has been securely fixed to the unit's trays or baskets. Make sure that the camera head does not touch other instruments.

3. Run an automated wash cycle with fundamentally approved efficiency of the washer-disinfector (for example, CE marking according to ISO 15883 or FDA approval/clearance/registration).

RECOMMENDED WASHING CYCLE PARAMETERS			
Phase	**Recirculation Time (Minutes)**	**Temperature**	**Detergent**
Pre-Wash 1	02:00	COLD UTILITY WATER	NA
Detergent Wash	03:00	FOLLOW DETERGENT MANUFACTURER'S RECOMMENDATION	Enzymatic or Alkaline Detergent
Rinse 1	00:15	HOT WATER	NA
Drying	06:00	90°C [194°F]	NA

4. Remove the camera heads immediately after the automated procedure has stopped.
5. Dry the equipment with a soft, low-linting cloth and/or filtered medical grade air. Wipe the card edge connector with 70% isopropyl alcohol to remove any residual detergent.
    a. **Do not allow exposed glass windows to air dry. 70% isopropyl alcohol may be applied to glass surfaces with a soft cotton applicator to prevent streaks and spots. Dry the surfaces thoroughly with a cotton applicator after applying the alcohol.**
6. After cleaning, inspect the camera head assembly and camera head cable for cleanliness and damage. Repeat cleaning if soil is visible and re-inspect; otherwise, proceed to Sterilization.
7. **CAUTION**: Inspect the camera head cable for breaks and cuts. Camera heads with damaged cables should not be sterilized or disinfected. Return camera heads with damaged cables to Arthrex for repair.
8. Before sterilization and/or disinfection, coil the camera head cable into loops at least six inches in diameter. Do not kink or twist the cable.

3.3.3.4 Manual Cleaning

CAUTION: Wear protective gloves, clothing and face mask for cleaning of contaminated equipment.

1. Immediately after use, rinse the camera head under cool running utility water to remove gross soil. Use a soft bristled brush to aid in the removal of soil paying particular attention to hard-to-clean areas.
2. Prepare a neutral pH enzymatic detergent solution using utility water.
3. Fully immerse the camera head in the prepared solution and allow it to soak for a minimum of 10 minutes. Flush hard to reach areas to ensure all soil is removed. While soaking, activate movable parts.
4. After soaking, use a soft bristled nylon brush to remove all visible evidence of debris and soil. Pay close attention to the card edge connector.
5. Rinse the camera head by immersing it in a basin of warm utility water. Allow the camera head to sit in the water for a minimum of 1 minute. While soaking, activate movable parts.
    a. Repeat step 5 two additional times using fresh warm utility water each time.
    b. Rinse under running utility water to ensure water reaches hard to reach areas. Activate while rinsing until all visible evidence of detergent is removed.
6. Visually inspect the camera head for visible soil. Repeat cleaning if soil is visible and re-inspect.
7. Dry the equipment with a soft, low-linting cloth and/or filtered medical grade air. Wipe the card edge connector with 70% isopropyl alcohol to remove any residual detergent.

a. **Do not allow exposed glass windows to air dry. 70% isopropyl alcohol may be applied to glass surfaces with a soft cotton applicator to prevent streaks and spots. Dry the surfaces thoroughly with a cotton applicator after applying the alcohol.**

8. After cleaning, inspect the camera head assembly and camera head cable for damage.
9. **CAUTION**: Inspect the camera head cable for breaks and cuts. Camera heads with damaged cables should not be sterilized or disinfected. Return camera heads with damaged cables to Arthrex for repair.
10. Before sterilization and/or disinfection, coil the camera head cable into loops at least six inches in diameter. Do not kink or twist the cable.

3.3.4 Sterilization of the AR-3210-XXXX Camera Heads

3.3.4.1 Sterile Packaging

Singly: Single devices should be packed as to ensure that the pack is large enough to contain the device without stressing the seals. Packaging should be completed utilizing a pouch or wrap which conforms to the recommended specifications for steam sterilization as outlined below. If a wrap is utilized, it should be completed following AAMI double-wrap or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body).

Sets: Where appropriate, cleaned and inspected devices should be placed into trays/cases as provided or in general-purpose sterilization trays. The total weight of trays/cases should not exceed 11.4 kg/25 lbs. (other local limits below 11.4 kg/25 lbs. may apply). Trays/cases should be double wrapped following AAMI or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body).

3.3.4.2 Sterilization

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table below. Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

PRECAUTION: After sterilization, ensure that the AR-3210 Camera Heads are allowed to adequately cool before connecting to the CCU or attaching to a scope.

RECOMMENDED STEAM STERILIZATION PARAMETERS				
Cycle	**Minimum Exposure Temperature**	**Minimum Exposure Time**	**Minimum Dry Time[1]**	**Minimum Cooling Time[2]**
Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes	30 Minutes
Gravity-Displacement (Wrapped)	132°C (270°F)	15 Minutes	30 Minutes	30 Minutes
Gravity-Displacement (Un-Wrapped)	132°C (270°F)	10 Minutes	NA	NA

[1]Drying times vary according to load size and should be increased for larger loads.
[2]Cooling times vary according to the sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

HYDROGEN PEROXIDE STERILIZATION METHODS The following cycles have been validated for AR-3210-XXXX Camera Heads to provide a sterility assurance level (SAL) of 10^{-6}.	
System	**Cycles**
Steris® Systems	• V-PRO® 1 Low Temperature Sterilization System [Standard Cycle] • V-PRO® 1 Plus Low Temperature Sterilization System [Lumen and Non-lumen Cycles] • V-PRO® maX Low Temperature Sterilization System [Lumen, Non-lumen and Flexible Cycles] • V-PRO® 60 Low Temperature Sterilization System [Lumen and Non-lumen Cycles]
Sterrad® Systems	• Sterrad® System 100S [Short Cycle] • Sterrad® System NX [Standard Cycle] • Sterrad® System 100NX [Standard Cycle]

3.3.5 Material Compatibility

In addition to the Sterilization chemicals listed above, the AR-3210-XXXX camera heads are Material Compatible with Cidex OPA. No SAL claims are made with Cidex OPA.

WARNING: Use of Sterilants or Chemicals other than those listed in the Cleaning and Sterilization section may result in the compromise of the device's safety and effectiveness. Use of Sterilants or Chemicals other than those listed in the "Cleaning, Disinfecting, and Sterilizing" section shall void the product's warranty.

3.4 Troubleshooting

Symptom	Possible Cause	Corrective Action
Camera does not power up. Standby LED does not illuminate.	• Power cord is unplugged. • Suspect power cord.	• Plug power cord into CCU and/or a properly grounded receptacle. • Replace power cord.
Intermittent picture.	• Verify camera head connector card edge is fully inserted into the CCU camera receptacle. • Suspect video and/or power cables. • Suspect camera head or cable.	• Reinsert camera head connector card edge. • Flex video and power cables. If picture is affected, inspect cables and replace as necessary. • Flex camera cable. If picture is affected, return to factory for repair or replacement.
Camera will not white balance.	• Too much light. • Too little light. • Wrong Color Temperature light.	• If monitor indicates “White Balance Fail”, move the scope further away from the white gauze when you white balance, or turn down the LED Light Engine brightness. • If monitor indicates “White Balance Fail”, move the scope closer to the white gauze when you white balance, or turn up the LED Light Engine brightness.
Camera head buttons do not function as programmed.	• Incorrect camera head button programming.	• Reprogram camera head buttons. NOTE: Tablet Data Input device option only.

Symptom	Possible Cause	Corrective Action
No video image on monitor.	• CCU and/or monitor are not ON and/or plugged in. • Equipment is not connected properly or cable(s) damaged. • Suspect camera head and/or cable. • Camera head cable connector not inserted correctly or completely.	• Plug CCU and/or monitor in and/or turn power ON. • Confirm cable connections and reroute video cables, if necessary, per interconnect diagram. Check video cables for damage, replace as necessary. • Replace the camera head with a working unit and verify image on monitor. If image is now viewed, the original camera head and/or cable were faulty, return them to Arthrex for repair. • Insert camera head cable connector completely into the CCU's camera head receptacle on the front panel. • Check monitor using color bars from the CCU. • Try the CCU on a different monitor.
Poor color reproduction.	• White Balance Issues.	• White Balance camera head. • Check monitor settings using color bars from the CCU. • Try the CCU on a different monitor.
System does not boot up correction/Banners do not display or do not display properly.	• Improper shut down of CCU.	• Power down device, wait 3 minutes, and restart system.
AR-3200-1013 Tablet will not connect to CCU.	• Software Incompatibility	• Synergy*UHD4* Software must be updated to v4.13.1 or newer.

Symptom	Possible Cause	Corrective Action
Tablet continually restarts or will not progress beyond the Samsung startup screen.	• Damage to Tablet • Improper Charger Used • Improper USB Charger extension cable used.	• Verify Tablet cable and connector are not damaged. If damaged, contact Arthrex Technical Support for further assistance. • Ensure charger is a Samsung mode EP-TA10JWE that has a minimum of 2.0A of charge current. Replace charger if it is not. Contact Arthrex Technical Support if problem persists. • Ensure USB charger cable is a USB 3.0 cable (both connectors) with a length that does not exceed 6 ft. (1.83 meters). Replace charger cable if it is not. Contact Arthrex Technical Support if problem persists.

3.5 Resolving Error Messages

Error Message	Corrective Action
Cannot connect to Synergy. Touch to try again.	If not resolved, contact Arthrex Technical Support for further assistance.
User account is locked.	Contact site administrator for assistance.
User not assigned to valid network group.	Contact site administrator for assistance.
The software update to <*new version*> failed and was automatically rolled back to <original version>.	The software update performed was not successful. The device has automatically rolled back to the software version before the attempted upgrade. Contact Arthrex Technical Support for further assistance.
Camera head is not compatible and should not be used in any surgical procedures with the current system	Refer to Instructions for Use for list of compatible Camera Heads.
Unfortunately, we were unable to restore the following items and they have been reset back to their default values.	Contact Arthrex Technical Support for further assistance.
An error occurred while fetching version info:	Contact Arthrex Technical Support for further assistance.
The Synergy console cannot be reached.	Contact Arthrex Technical Support for further assistance.
Failed to install updated controller.	Contact Arthrex Technical Support for further assistance.

3.6 Recommended Annual Camera Control Unit Maintenance Requirements

Recommended Annual Camera Control Unit Maintenance Requirements	
Test Type	**Test Value**
Ground Impedance	ZG < 100 mOhm from the ground pin on the power inlet module to the Camera Control Unit's exposed metal parts. *
Test Chassis Leakage Currents	IL < 100 µA in NORMAL Condition. IL < 500 µA in Single Fault Conditions [300 µA US deviation] *
Test Earth Leakage Currents	IL < 5 mA NORMAL Condition IL < 10 mA Single Fault Condition *
Test Dielectric Withstand	Test Line and Neutral to Ground @ V = 1500 V~, no breakdown *
*** See IEC 60601-1 for test methods.**	

4.0 Technical Information

NOTE: Technical data is subject to modification, revision and improvement without notice.

Safety, EMC and Regulatory Requirements		
Parameter	**Parameter Value**	
System Classification	FDA Class	Class II
	EU Class	Class IIa
	Health Canada Class	Class II
Safety Certifications	Domestic Certification	• ANSI/AAMI ES60601-1/A1:2012
	Canadian Certification	• CAN/CSA-C22.2 No. 601.1-M90 • CAN/CSA-C22.2 No. 60601-1:2014
	EU Certification	• ANSI/AAMI ES60601-1/A1:2012 • IEC 60601-1:2005 + Corrigendum 1:2006 + Corrigendum 2:2007 + AM1:2012 [IEC 60601-1:2012]
EMC Certifications	CISPR 11 EMC Class	Class A
	CISPR 11 EMC Group	Group 1 [RF internally generated for the operation of the device]
	EMC Certification	Certification to IEC 60601-1-2:2014 Class A
Safety Certification Marking		
CE Marking	CE Marking for MDD 93/42/EEC, RoHS 2011/65/EU, and (RED)(2014/53/EU)	

Safety, Classifications	
Classification of Equipment	**Parameter Value**
According to protection against electric shock.	Class I [Grounded]
According to degree of protection against electric shock.	Applied part is Type CF Defibrillation Proof
According to Degree of protection against harmful ingress of water.	Camera Control Units are Ordinary [IPX-0] no protection. Camera Head is IXP-7 [Protected against temporary immersion in water]
According to the degree of safety in the presence of Flammable Anesthetics	Equipment is NOT suitable for use in the presence of flammable anesthetics.
According to the mode of operation.	Continuous

Specifications		
Parameter	**Parameter Value**	
Power Requirements	Rated Voltage: Supply Frequency: Power Input: Fuses:	100 – 240 VAC 50-60 Hz 160 VA No user serviceable fuses
Video Outputs	**Video Output**	**Description**
	Display Port (2x)	3840 x 2160 pixels [4K/UHD], 10-bit color
	DVI (2x)	1920 x 1080 pixels [1080p], 8-bit color
	3G-SDI (4x)	1920 x 1080 pixels [1080p], 8-bit color
	Matrix Video (2x)	3840 x 2160 pixels [4K/UHD], 8-bit color (AR-3200-0020 [CCU, Synergy^{UHD4}, Matrix] and AR-3200-0022 [CCU, Synergy^{UHD4}, Matrix, HCRI])
Vertical Scanning Frequency	59.94 Hz	
Signal to Noise Ratio	> 52 dB [4K] > 48 dB [HD]	
White Balance Range (using CCU Light Source)	2500 – 9000 K [4K] 2000 – 9000 K [HD]	
CCU Dimensions	Approximately:	17” [W] x 3.5” [H] x 13.5” [D] 43.2 cm [W] x 8.9 cm [H] x 34.3 cm [D]
CCU Weight	Approximately:	15 pounds/6.8 kg

Camera Head Dimensions	**AR-3210-0018** Approximately	4” [L] x 1.8” [W], x 1.8” [H] 10.1 cm [L] x 4.5 cm [W] x 4.5 cm [H]
	AR-3210-0021 Approximately	2.7” [L] x 1.2” [W], x 1.3” [H] 6.9 cm [L] x 3.0 cm [W] x 3.3 cm [H]
	AR-3210-0022 Approximately	2.7” [L] x 1.7” [W], x 1.7” [H] 6.9 cm [L] x 4.3 cm [W] x 4.3 cm [H]
	AR-3210-0023 Approximately:	4.1” [L] x 1.8” [W], x 1.8” [H] 9.9 cm [L] x 4.6 cm [W] x 4.6 cm [H]
	AR-3210-0025 Approximately:	2.8” [L] x 1.65” [W], x 1.7” [H] 7.1 cm [L] x 4.2 cm [W] x 4.3 cm [H]
	AR-3210-0026 Approximately:	2.9” [L] x 1.2” [W], x 1.3” [H] 7.3 cm [L] x 3.0 cm [W] x 3.3 cm [H]
	AR-3210-0028 Approximately:	2.8” [L] x 1.65” [W], x 1.7” [H] 7.1 cm [L] x 4.2 cm [W] x 4.3 cm [H]
	AR-3210-0029 Approximately:	4.1” [L] x 1.8” [W], x 1.8” [H] 9.9 cm [L] x 4.6 cm [W] x 4.6 cm [H]
	AR-3210-0030 Approximately:	2.8” [L] x 1.65” [W], x 1.7” [H] 7.1 cm [L] x 4.2 cm [W] x 4.3 cm [H]
	AR-3210-0031 Approximately:	4.5” [L] x 2.0” [W], x 2.0” [H] 11.4 cm [L] x 5.1 cm [W] x 5.1 cm [H]
	AR-3210-0032 Approximately:	3.5” [L] x 2.0” [W], x 2.0” [H] 8.9 cm [L] x 5.1 cm [W] x 5.1 cm [H]

Camera Head Weight	**AR-3210-0018** Approximately	19.6 ounces [0.6 kg]
	AR-3210-0021 Approximately	17.1 ounces [0.5 kg]
	AR-3210-0022 Approximately	17.9 ounces [0.5 kg]
	AR-3210-0023 Approximately	21.0 ounces [0.6 kg]
	AR-3210-0025 Approximately	17.4 ounces [0.5 kg]
	AR-3210-0026 Approximately	17.4 ounces [0.5 kg]
	AR-3210-0028 Approximately:	27.4 ounces [0.8 kg]
	AR-3210-0029 Approximately:	21.0 ounces [0.6 kg]
	AR-3210-0030 Approximately:	17.4 ounces [0.5 kg]
	AR-3210-0031 Approximately:	20.8 ounces [0.6 kg]
	AR-3210-0032 Approximately:	17.5 ounces [0.5 kg]
Transport & Storage Conditions	Ambient Temperature:	-40°F to 122°F [-40°C to 50°C]
	Relative Humidity:	10% to 90%, non-condensing
	Atmospheric Pressure:	500 hPa to 1060 hPa
Operating Conditions	Ambient Temperature:	+50°F to 73°F [10°C to 23°C]
	Relative Humidity:	30% to 75%, non-condensing
	Atmospheric Pressure:	Altitudes ≤ 3000 m

LED Light Engine Specifications			
Parameter	**Parameter Value**		
LED Light Engine Specifications	Light output	Standard	Minimum: 1600 Lumens Typical; 1800 Lumens
		HCRI	Minimum: 1000 Lumens Typical; 1125 Lumens
	Color Temp	Standard	70 CRI Typical, 65 Minimum 5500-8500K
		HCRI	92 CRI Typical, 90 Minimum 5200-6700K
	LED Life	> 30,000 hours	
	Light Guide Port Turret	ACMI™ Standard, Storz™, Wolf™ and Olympus™	

DICOM Specifications
DICOM Statement
DICOM Compatible with installation of AR-3200-1020 DICOM Key

5.0 APPENDIX [Radio Module Information]

FCC Information:

Contains FCC ID: RYK-261ACNBT

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions; (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation

 CAUTION: changes or modifications not expressly approved by Arthrex will void the user's authority to operate this equipment.

Industry Canada Information:

Contains IC: 6158A-261ACNBT
IC Model: WPEQ-261ACN(BT)

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions; (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation

European Union Information:

Compliant with (RED)(2014/53/EU)

6.0 APPENDIX [Detailed EMC Information]

DETAILED EMC INFORMATION

NOTE: CE marked equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC [EN 55011 Class A and IEC 60601-1-2]. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The Equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer or a field service technician for assistance.

NOTE: The EMC tables and other guidelines that are included in the Instruction Manual provide information to the customer or user that is essential in determining the suitability of the Equipment or System for the Electro-magnetic Environment of use, and in managing the Electromagnetic Environment of use to permit the Equipment or System to perform its intended use without disturbing other Equipment and Systems or non-medical electrical equipment.

NOTE: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents.

WARNINGS:

1. **Portable and mobile RF communications equipment can affect Medical Electrical Equipment.**
2. **Use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions and decreased immunity of the equipment or system.**
3. **The video equipment / system should not be used adjacent to or stacked with other equipment, and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it is intended to be used.**
4. **Under extreme conditions of primary power voltage sag [Primary voltage less than 60% of mains] the device may require operator intervention to recover lost image. Device may have to be restarted by pressing On/Standby Switch.**

IEC 60601-1-2 Guidance and manufacturer's declaration – electromagnetic emissions		
The Arthrex Synergy*UHD4* Video System is intended for use in the electromagnetic environment specified below. The customer or the user of the Arthrex Synergy*UHD4* Video System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment- guidance**
RE emissions CISPR 11	Group 1	The Arthrex Synergy*UHD4* Video System uses RF energy only for its internal function. Therefore its RF emissions are very low and not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class A	The Arthrex Synergy*UHD4* Video System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Arthrex*UHD4* Video System or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

System Cables				
Type	**Use**	**Shielded?**	**Ferrite?**	**Maximum Length**
Power Cord	Supply Line Power to the Box	No	No	2.0 M (6.6 ft)
BNC to BNC	Composite Video Out to Monitor	Yes	No	1.8 M (5.9 ft)
Display Port	Display Port Output to Video Monitor	Yes	Yes	2.0 M (6.6 ft)
DVI	DVI Video Out to Monitor	Yes	Yes	2.0 M (6.6 ft)
3 pin mini Stereo	Accessory Port	Yes	No	1.8 M (5.9 ft)
Ethernet	CCU to Computer	Yes	No	5.0 M (16.4 ft)
USB	CCU to Printer	Yes	No	1.8 M (5.9 ft)

IEC 60601-1-2 Guidance and manufacturer's declaration – electromagnetic immunity			
The Arthrex Synergy*UHD4* Video System is intended for use in the electromagnetic environment specified below. The customer or user of the Arthrex Synergy*UHD4* Video System should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge [ESD] IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered by synthetic material the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV differential mode ± 1 kV for input / output lines 100 khz Cycling Frequency	± 2 kV differential mode ± 1 kV for input / output lines 100 khz Cycling Frequency	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode. ± 2 kV common mode.	± 1 kV differential mode. ± 2 kV common mode.	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	U_T= 0%,0.5 cycle (0, 45, 90,135, 180, 225, 270, and 315^0) U_T= 0%;1 cycle U_T= 70%;25/30 cycles (@0 degrees) U_T= 70%; 250/300 cycles	U_T= 0%,0.5 cycle (0, 45, 90,135, 180, 225, 270, and 315^0) U_T= 0%;1 cycle U_T= 70%;25/30 cycles (@0 degrees) U_T= 70%; 250/300 cycles	Mains power should be that of a typical commercial or hospital environment. If the user of the Arthrex Synergy*UHD4* Video System requires continued operation during power mains interruptions, it is recommended that the Arthrex Synergy*UHD4* Video System be powered from an uninterruptible power supply. If voltage dips or short interruptions do occur the CCU will recover in < 5 seconds but the LED Light Source may be in stand-by. User will need to turn on the LED Light Engine with the front panel button.
Power Frequency [50/60 Hz] magnetic field. IEC 61000-4-8	3 A/m	3 A/m @50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U^T is the a.c. mains voltage prior to application of the test level.			

IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic immunity

The Arthrex Synergy*UHD4* is intended for use in the electromagnetic environment specified below. The customer or user of the Arthrex Synergy*UHD4* should ensure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	**V1=3 Vrms**	Portable and mobile RF communications equipment should be used no closer to any part of the Arthrex Synergy*UHD4* Video System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3.5 / V1]\sqrt{P}$ = 1.17 $\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	**E1= 3 V/m**	$d = [3.5 / V1]\sqrt{P}$ =1.17 $\sqrt{P}$ 80 MHz to 800 MHz $d = [7 / E1]\sqrt{P}$ = 2.33 $\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation in meters [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less that the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio [cellular/cordless] telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Arthrex Synergy*UHD4* Video System is used exceeds the applicable RF compliance level, above, the Arthrex Synergy*UHD4* Video System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Arthrex Synergy*UHD4* Video System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

IEC 60601-1-2

Recommended separation distances between portable and mobile RF communications equipment and the Arthrex Synergy*UHD4* Video System

The Arthrex Synergy*UHD4* Video System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Arthrex Synergy*UHD4* Video System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment [transmitters] and the Arthrex Synergy*UHD4* Video System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = [3.5/V1]\sqrt{P}$	**80 MHz to 800 MHz** $d = [3.5/E1]\sqrt{P}$	**800 MHz to 2.7 GHz** $d = [7/E1]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.14	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance [d] in meters [m] can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output rating of the transmitter in watts [W] according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

7.0 APPENDIX [SW Version access]

ACCESS to SW Version on Synergy*UHD4*

1. On POWER ON, the screen below appears.
2. Double click on screen to pull up SW Version.
3. Then Tap “About”

Figure 38 - Logging on to Android

Figure 39 - About Screen

Figure 40 - SW Version Screen

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